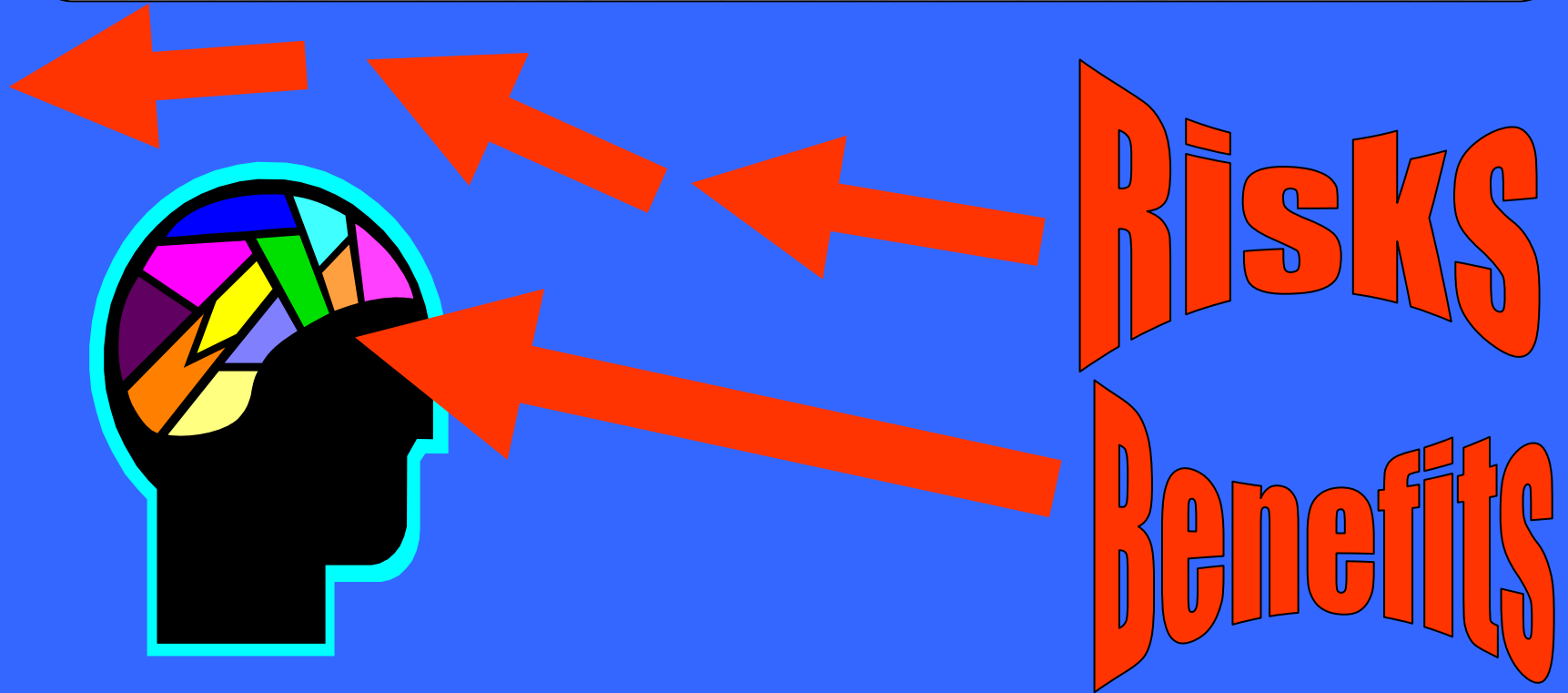


Comprehension of Benefits vs. Risks: Fair Balance in DTC?

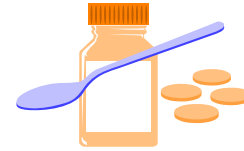


Ruth S. Day / Duke University

DTC Public Meeting
FDA / DDMAC, November 1, 2005

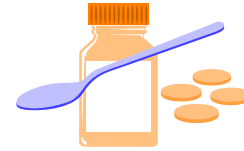
QUESTION:

**How do people understand
risk information?**



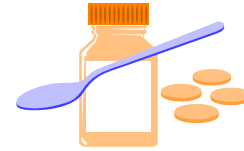
QUESTION:

How do people understand risk information?



ANSWER: With difficulty!

QUESTION:



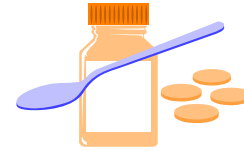
How do people understand risk information?

ANSWER: With difficulty!

WHY:

- Heavy information load**
- Complex/technical information**
- etc.**

QUESTION:

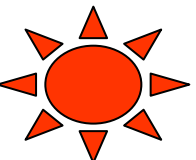


How do people understand risk information?

ANSWER: With difficulty!

WHY:

- Heavy information load
- Complex/technical information
- etc.
- Cognitive IN-Accessibility**

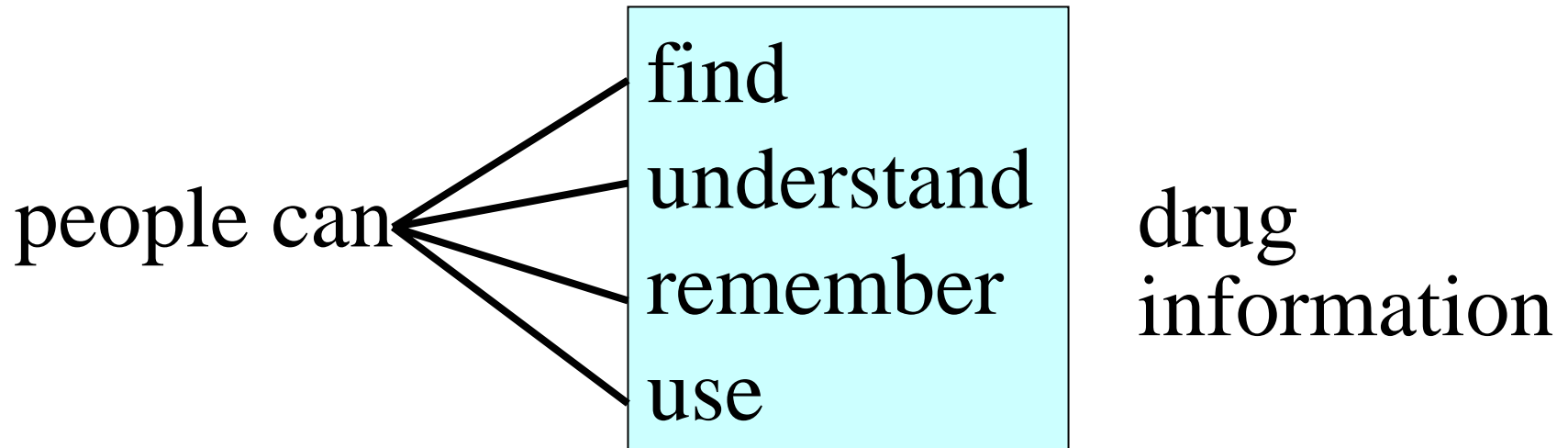


Cognitive Accessibility

The ease with which

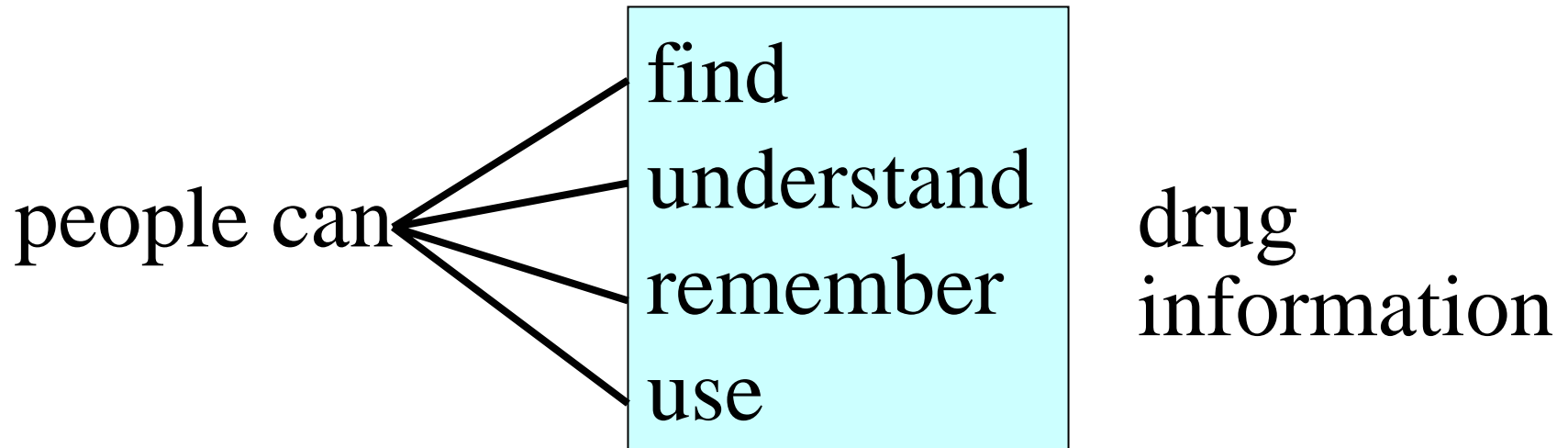
Cognitive Accessibility

The ease with which



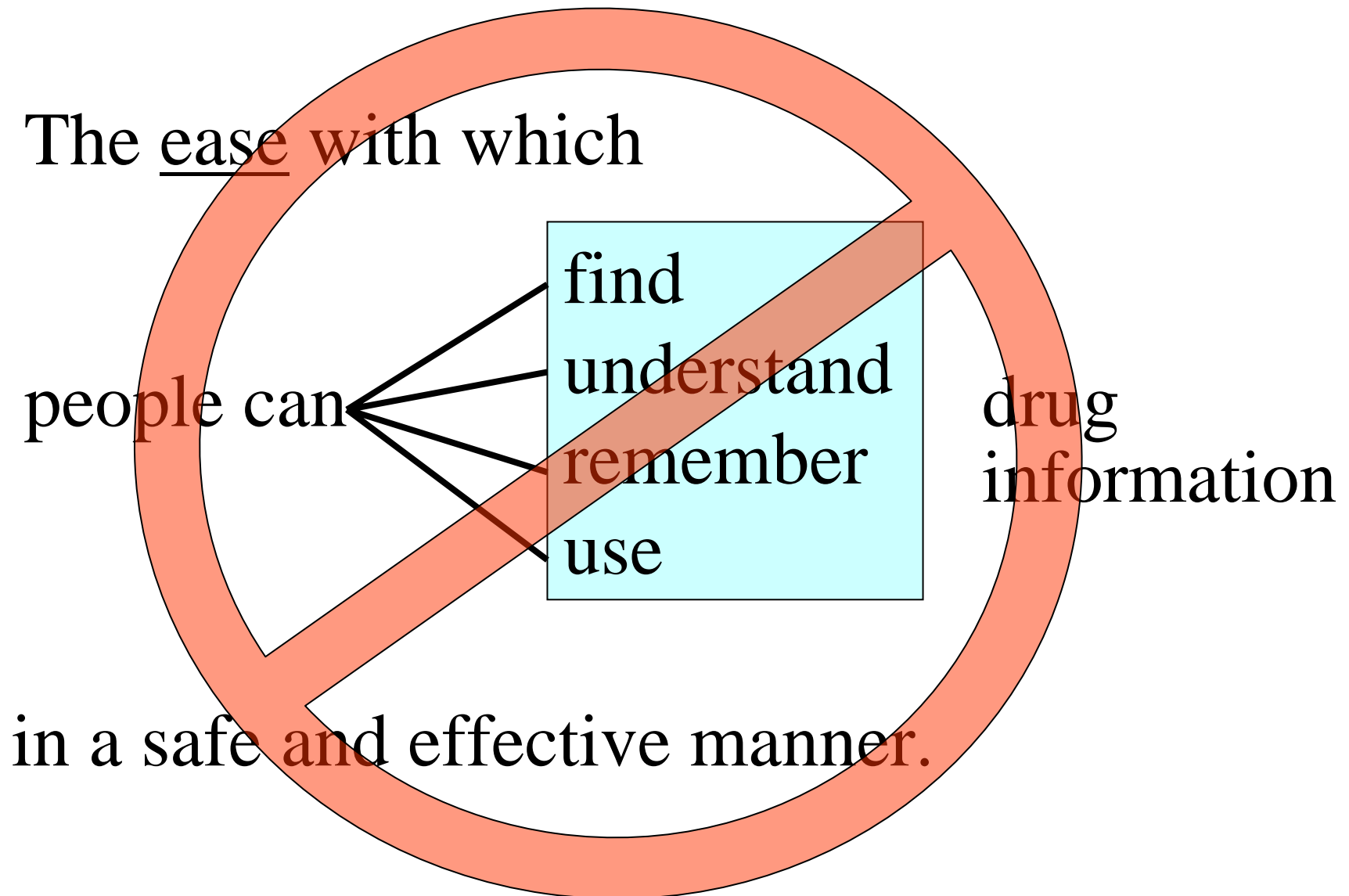
Cognitive Accessibility

The ease with which



in a safe and effective manner.

Cognitive **IN**-Accessibility

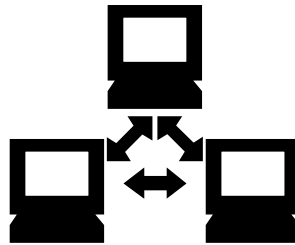


TYPES of INFORMATION

TV Ads



Internet



Hardcopy



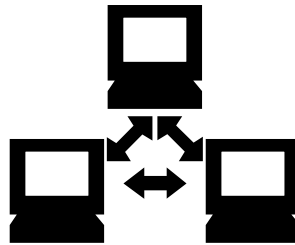
TYPES of INFORMATION

TV Ads



Rx Ads

Internet



Hardcopy



Professional Label
Patient Package Inserts
Medication Guides
Pharmacy Leaflets
Print Ads
OTC packages

BASIC APPROACH

```
graph TD; A["BASIC APPROACH"] --> B["Cognitive Analyses"]; A --> C["Enhanced Displays"]; A --> D["Cognitive Experiments"];
```

**Cognitive
Analyses**

**Enhanced
Displays**

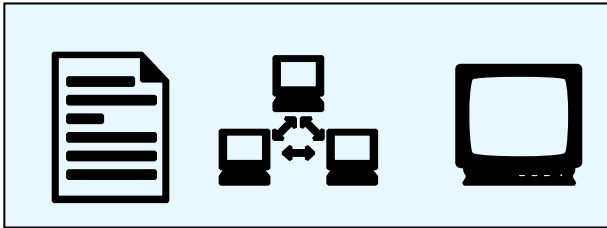
**Cognitive
Experiments**

BASIC APPROACH

**Cognitive
Analyses**

**Enhanced
Displays**

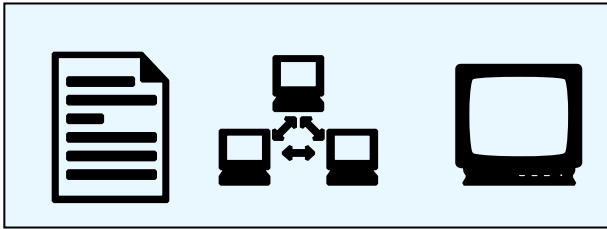
**Cognitive
Experiments**



- Obtain quantitative measures
- Calculate “cognitive accessibility”
- Compare benefits vs. risks

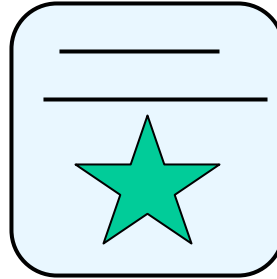
BASIC APPROACH

Cognitive Analyses



- Obtain quantitative measures
- Calculate “cognitive accessibility”
- Compare benefits vs. risks

Enhanced Displays

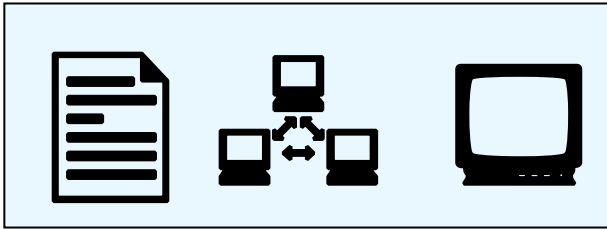


- Same info
- Based on cognitive principles

Cognitive Experiments

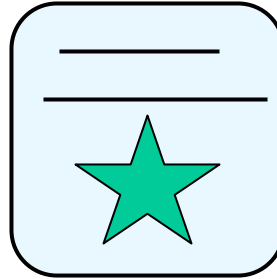
BASIC APPROACH

Cognitive Analyses



- Obtain quantitative measures
- Calculate “cognitive accessibility”
- Compare benefits vs. risks

Enhanced Displays



- Same info
- Based on cognitive principles

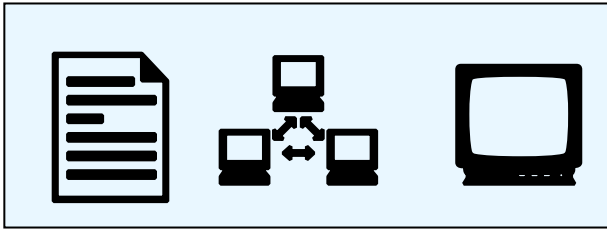
Cognitive Experiments

Test effects on:

- Attention
- Comprehension
- Memory
- Problem Solving
- Decision Making
- Behavior

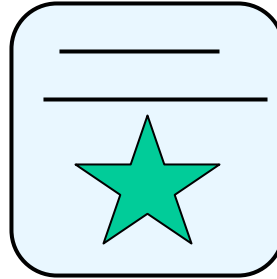
BASIC APPROACH

Cognitive Analyses



- Obtain quantitative measures
- Calculate “cognitive accessibility”
- Compare benefits vs. risks

Enhanced Displays



- Same info
- Based on cognitive principles

Cognitive Experiments

Test effects on:

- Attention
- Comprehension
- Memory
- Problem Solving
- Decision Making
- Behavior

Health Outcomes

COGNITIVE PRINCIPLES

Information Load

Chunking

Coding

Representation

Location

Speed

Readability

Comprehension

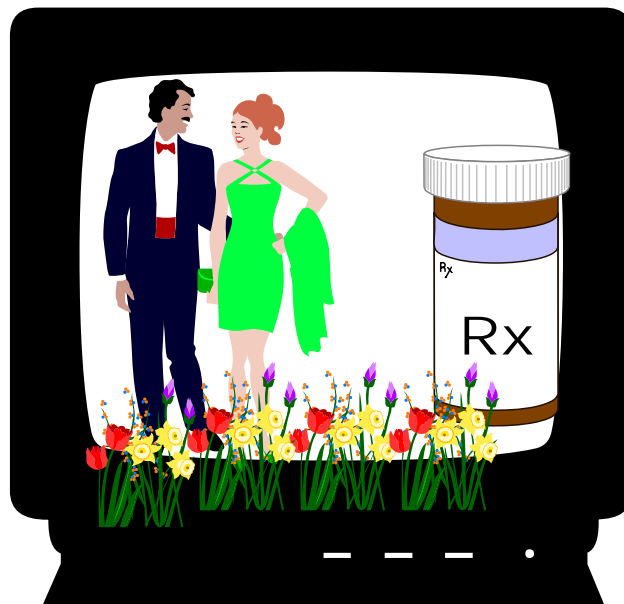
Prior Knowledge

Attention

Cognitive Task

Metacognition

Rx TV Ads



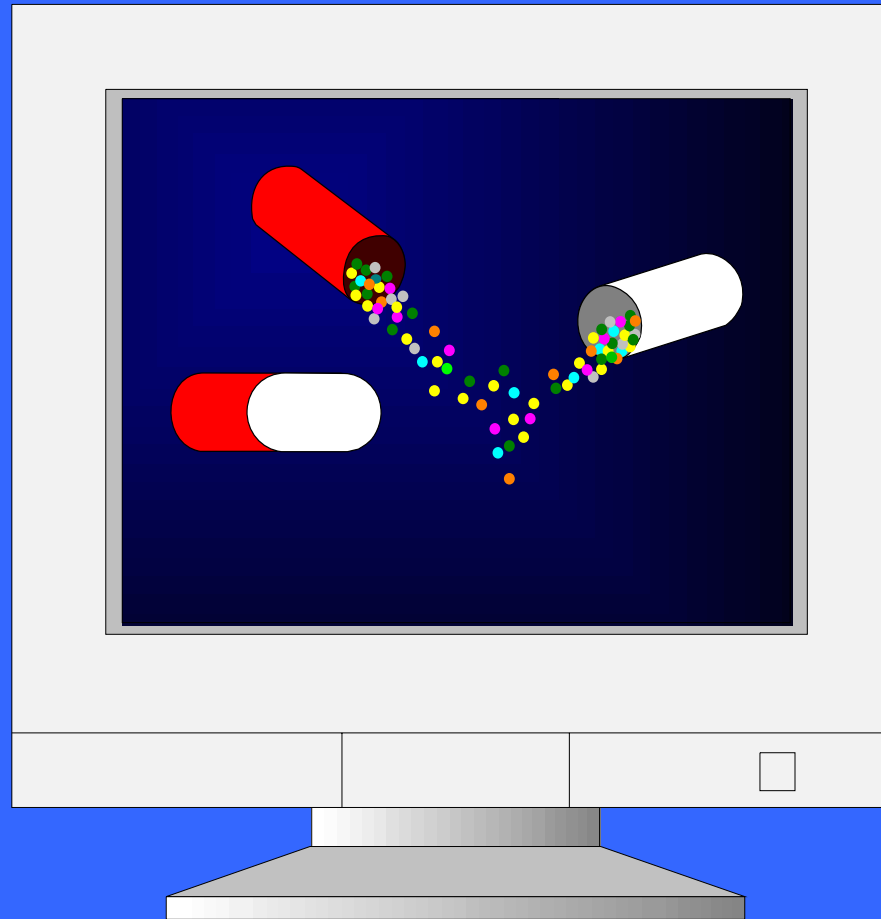
Time Period

2000-2001

2005



Experiments



Experiments

time



See ad

(N = 1-3)

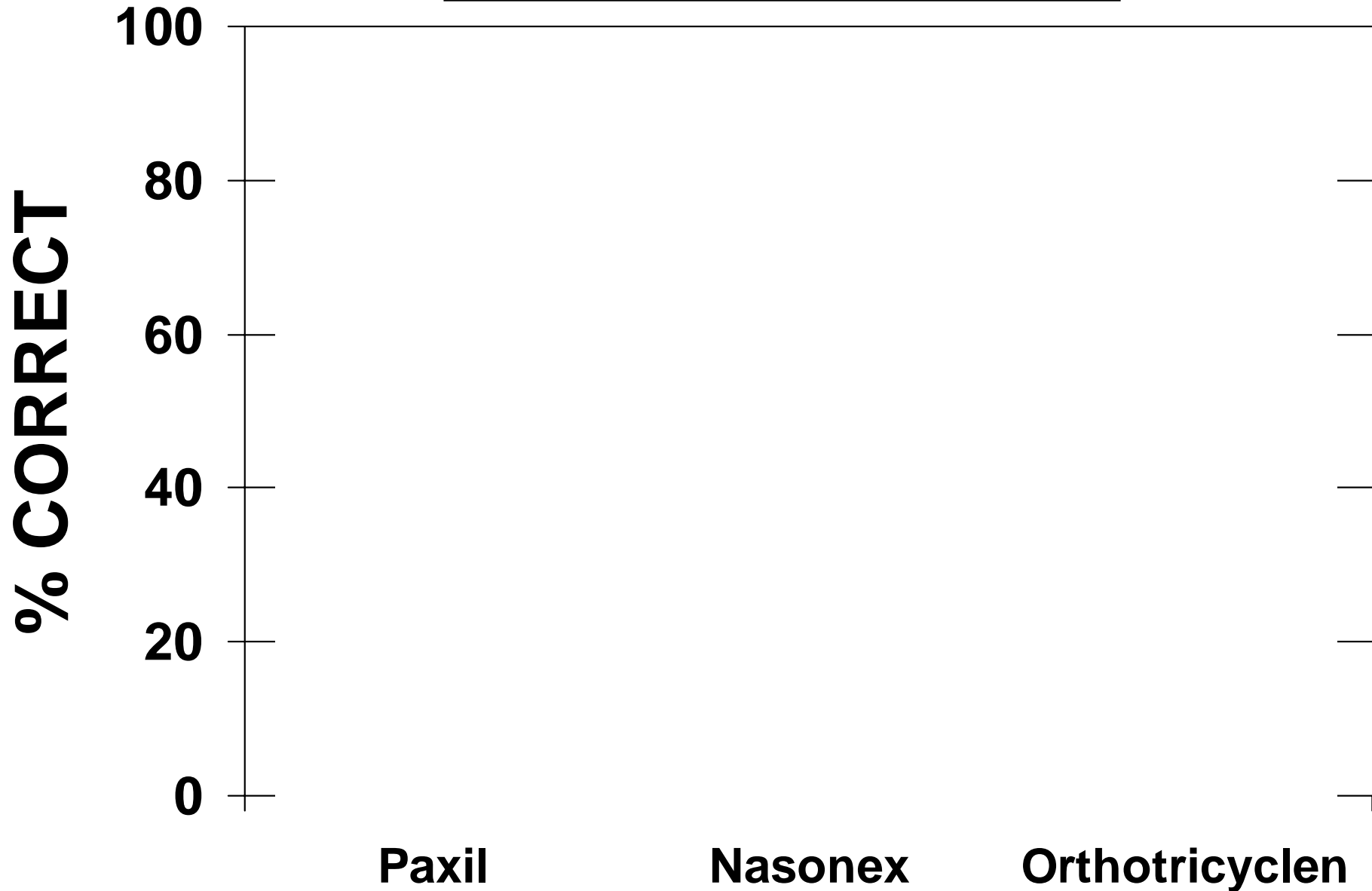
Test

Benefits

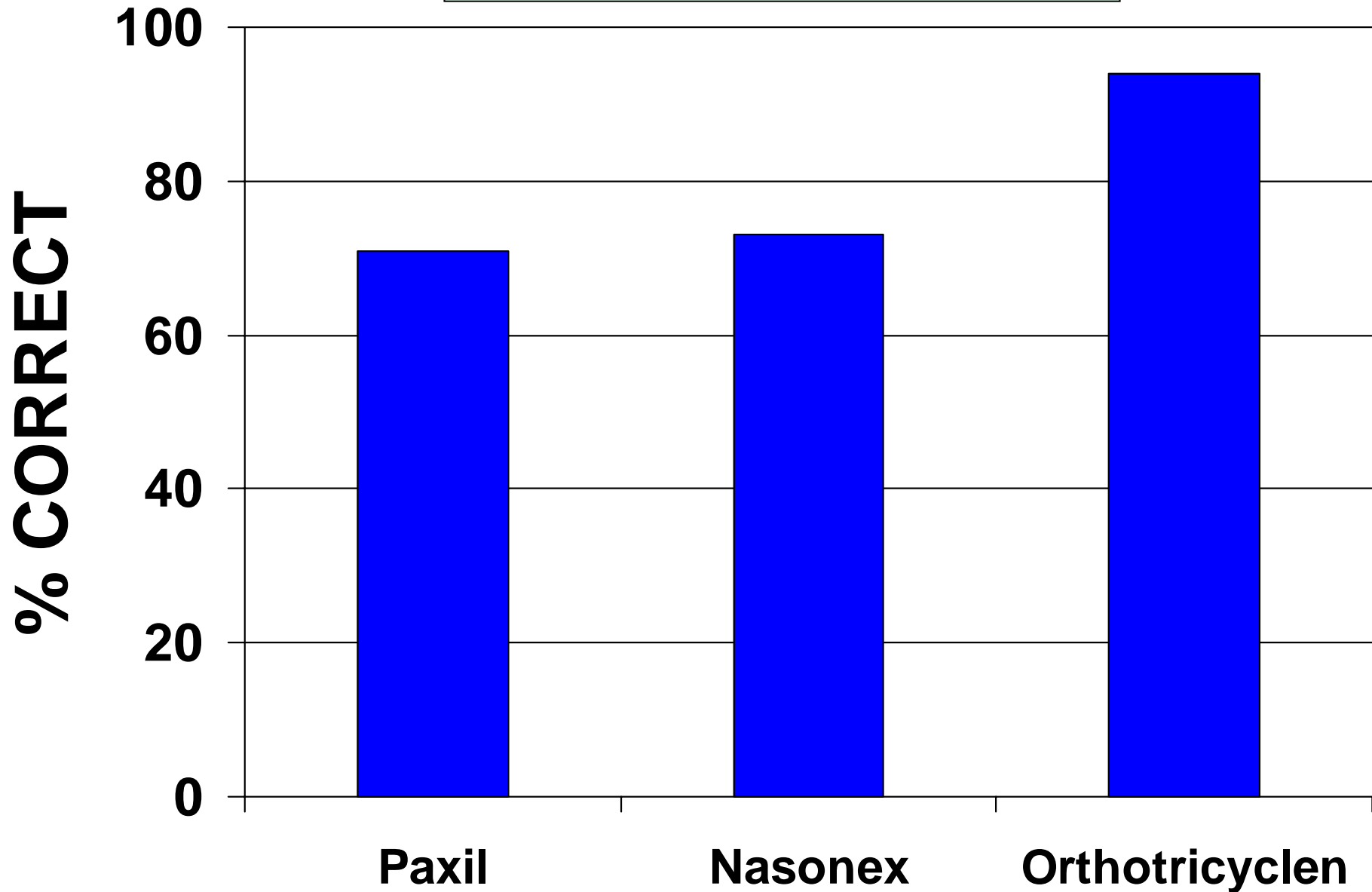
Risks

Other

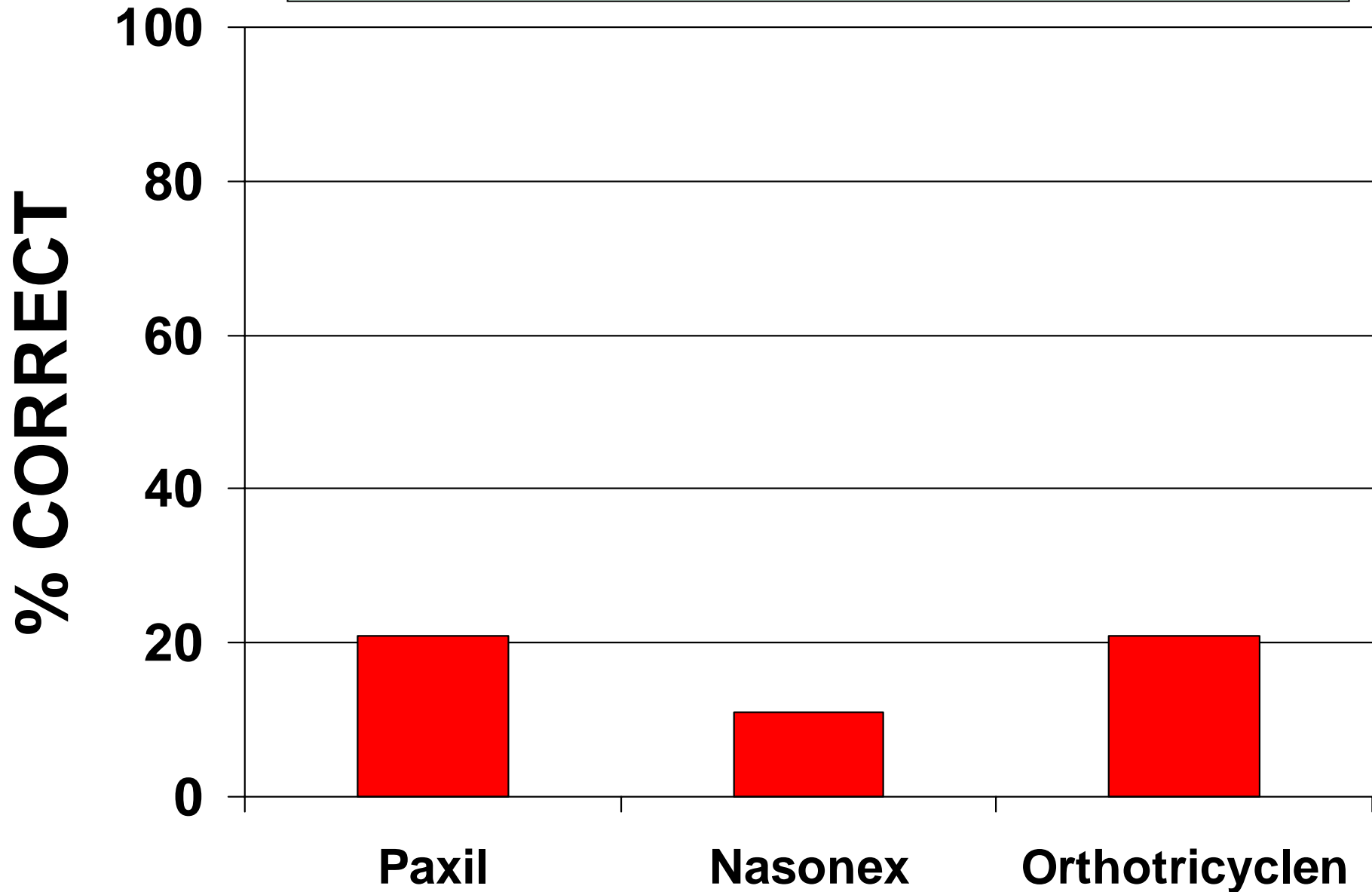
“What is it for?”



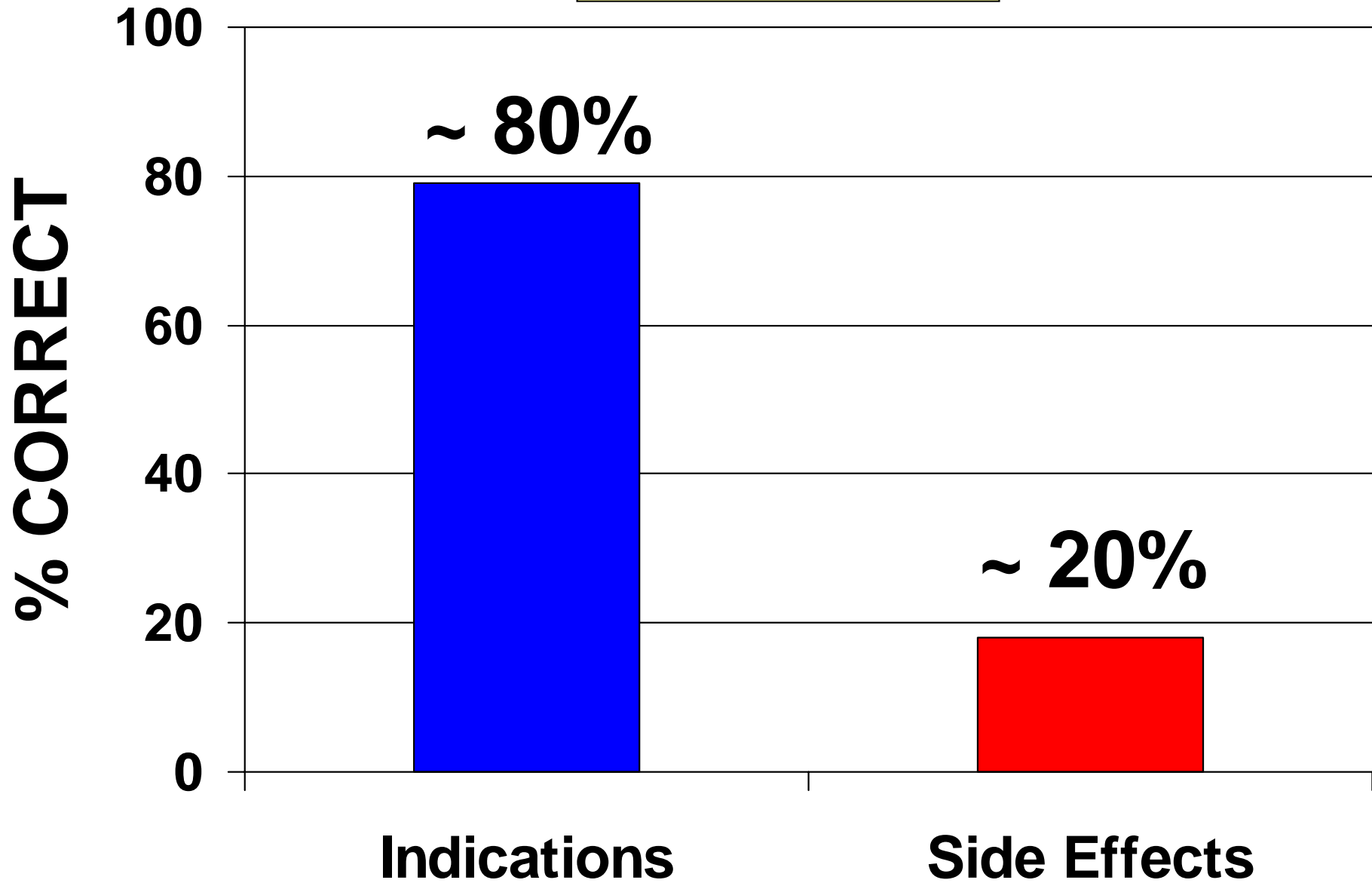
“What is it for?”

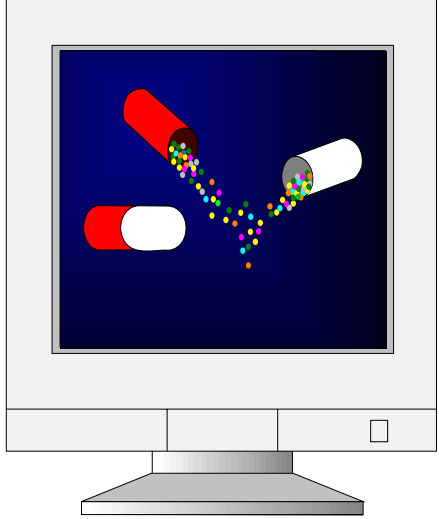


“What are the side effects?”



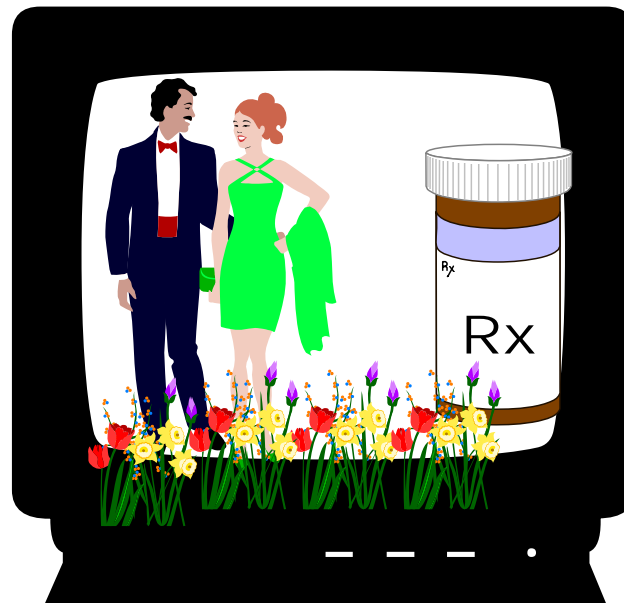
Overall





Why hard?

Rx TV Ads



Script

- Benefits
- Risks
- etc.

READABILITY

READABILITY

Readability \neq Comprehensibility

READABILITY

Readability ~~≠~~ Comprehensibility

However,

- easy to measure
- has predictive value
- therefore = quick “proxy” for
comprehensibility

2001

Rx Drug Ads

A l l e g r a	L i p i t o r	R e m i c a d e
A m b i e n	M e r i d i a	S e r e v e n t
C e l e b r e x	N a s o n e x	S i n g u l a i r
C l a r i t i n	O r t h o t r i c y c l e n	S o n a t a
D e n a v i r	P a t a n o l	T a m i f l u
D i f l u c a n	P a x i l	V a l t r e x
F l o n a s e	P r a v a c h o l	V i o x x
F l o v e n t	P r e v a c i d	W e l l b u t r i n S R
I m i t r e x	P r i l o s e c	Z y r t e c
L a m i s i l	P r o c r i t	

READABILITY

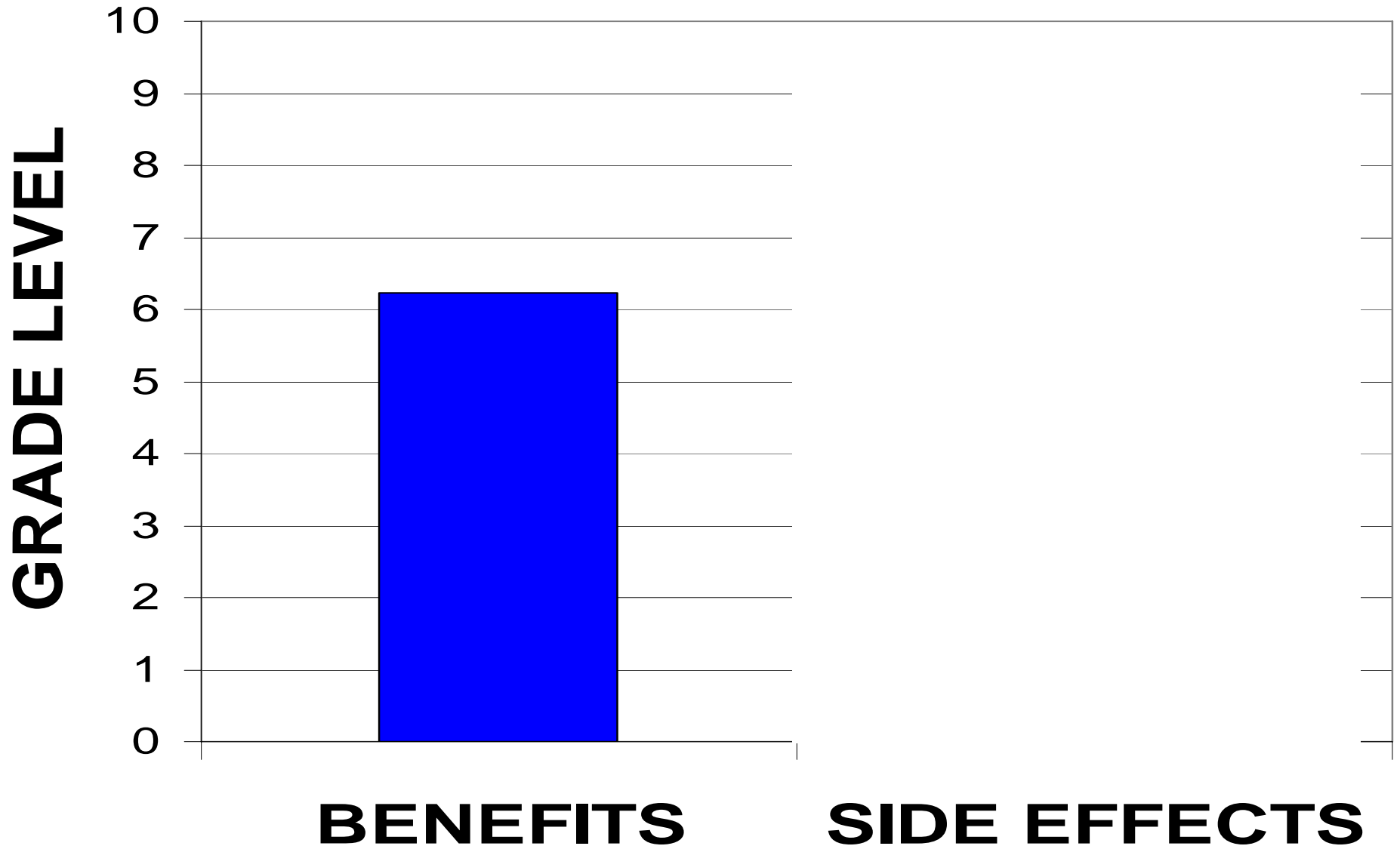
GRADE LEVEL

10
9
8
7
6
5
4
3
2
1
0

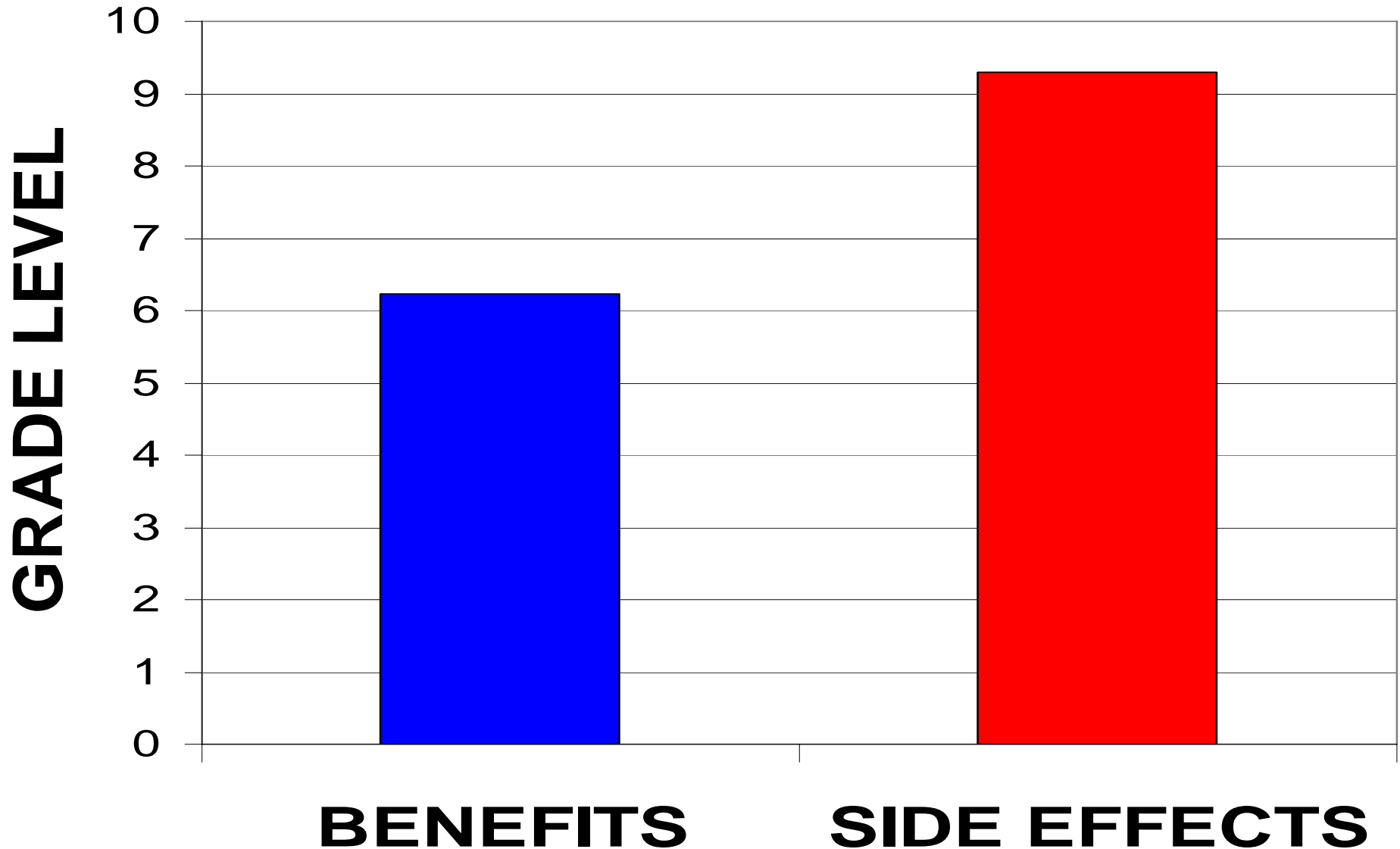
BENEFITS

SIDE EFFECTS

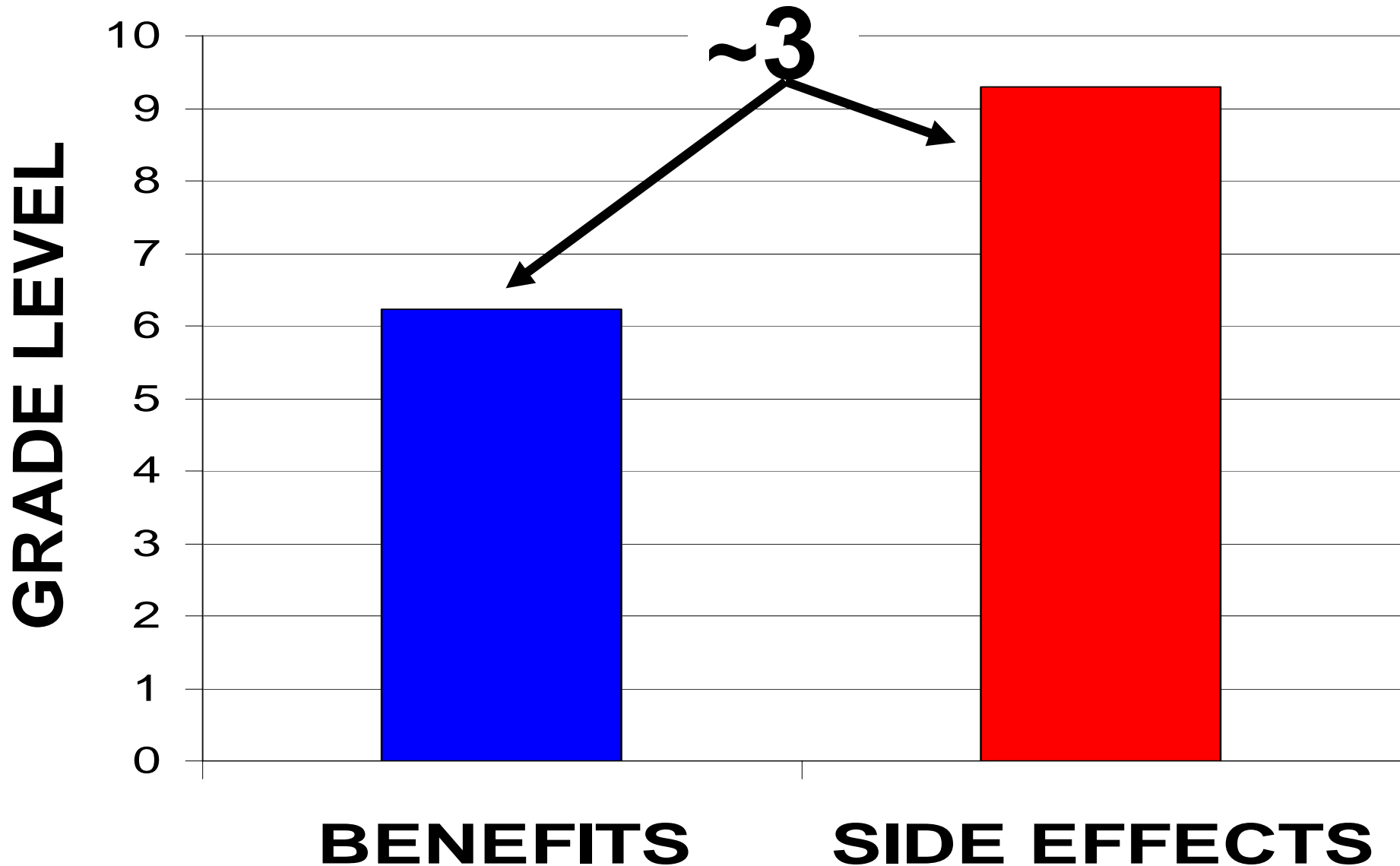
READABILITY



READABILITY



READABILITY



2005

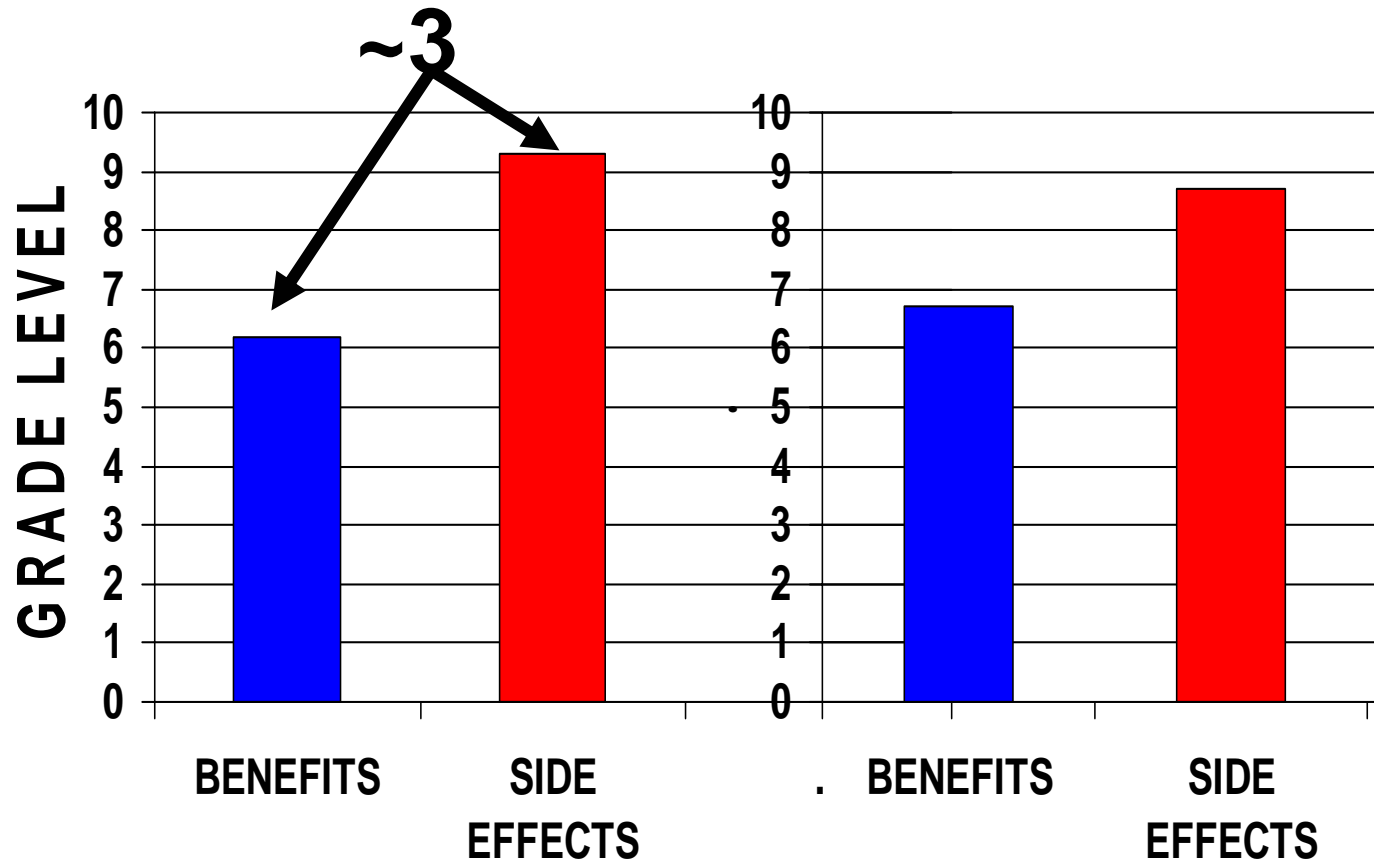
Rx Drug Ads

Ambien	Lipitor	Procrit
Avodart	Lunesta	Restasis
Boniva	Nasonex	Singulair
Cialis	Nexium	Valtrex
Detrol-LA	OrthoEvra	Vesicare
Ditropan-XL	Orthotricyclen	Vytorin
Fosamax	Patanol	Welbutrin-XL
Humira	Plavix	Zelnorm
Imitrex	Premarin	Zyrtec

READABILITY

2001

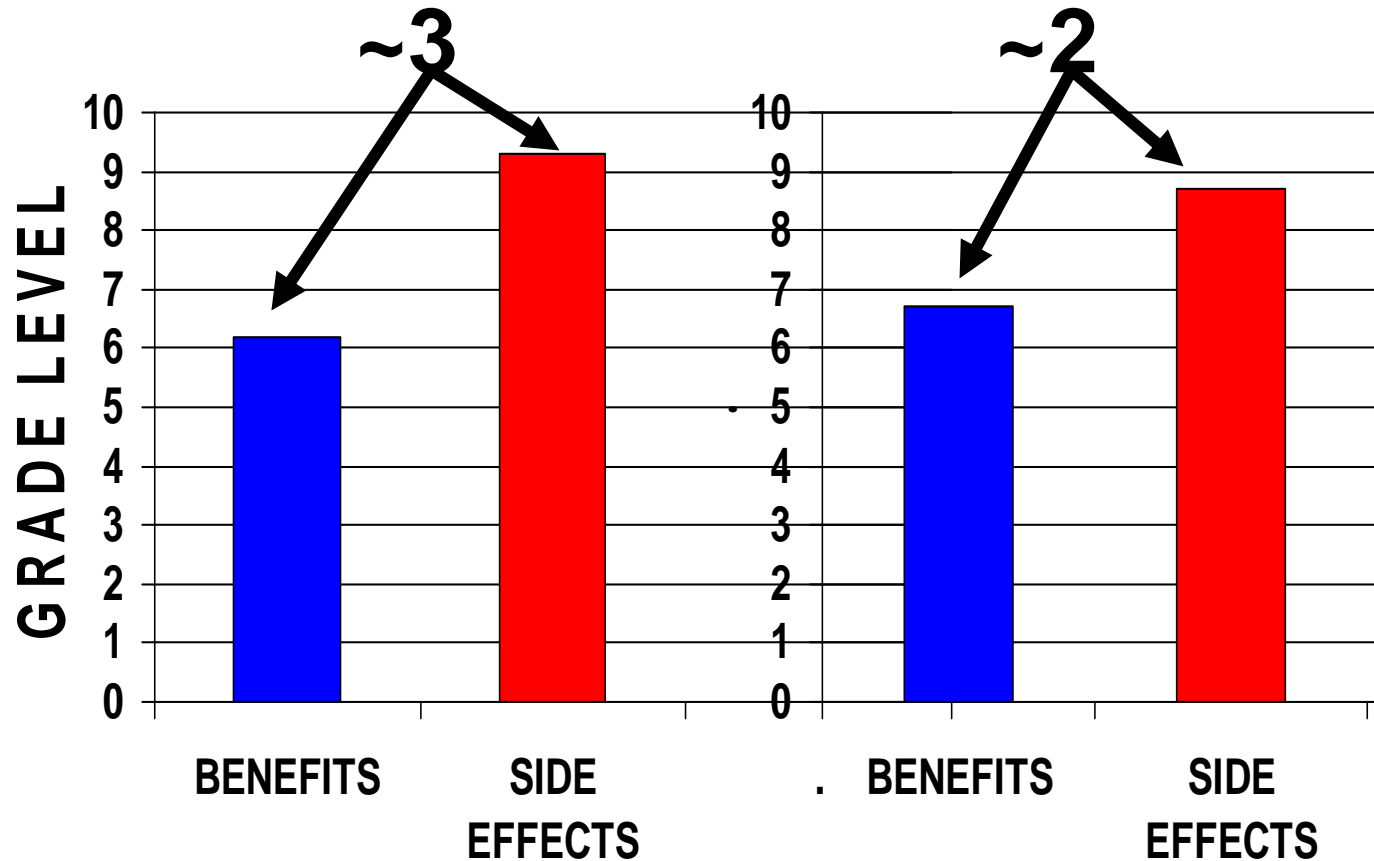
2005



READABILITY

2001

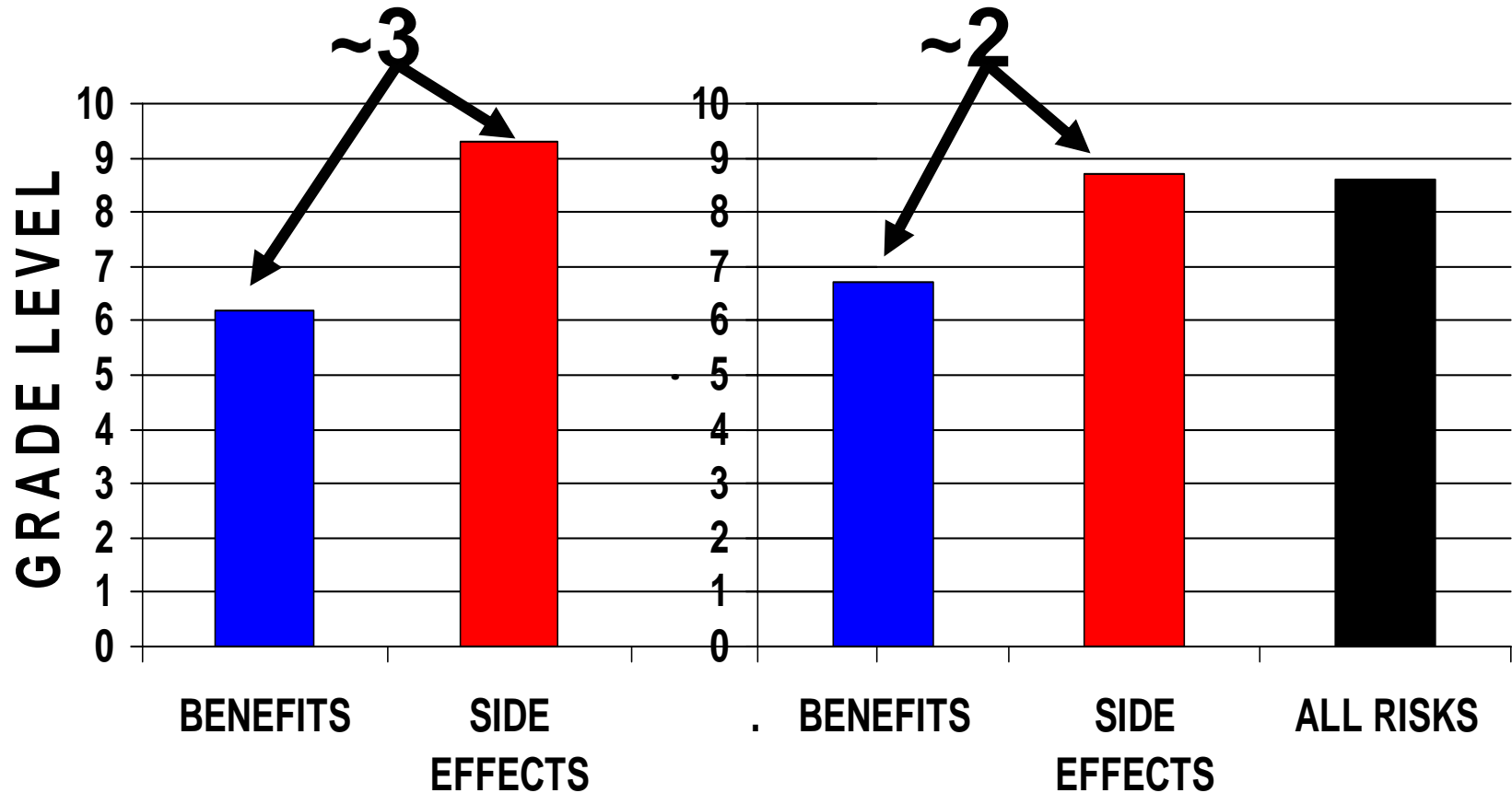
2005



READABILITY

2001

2005

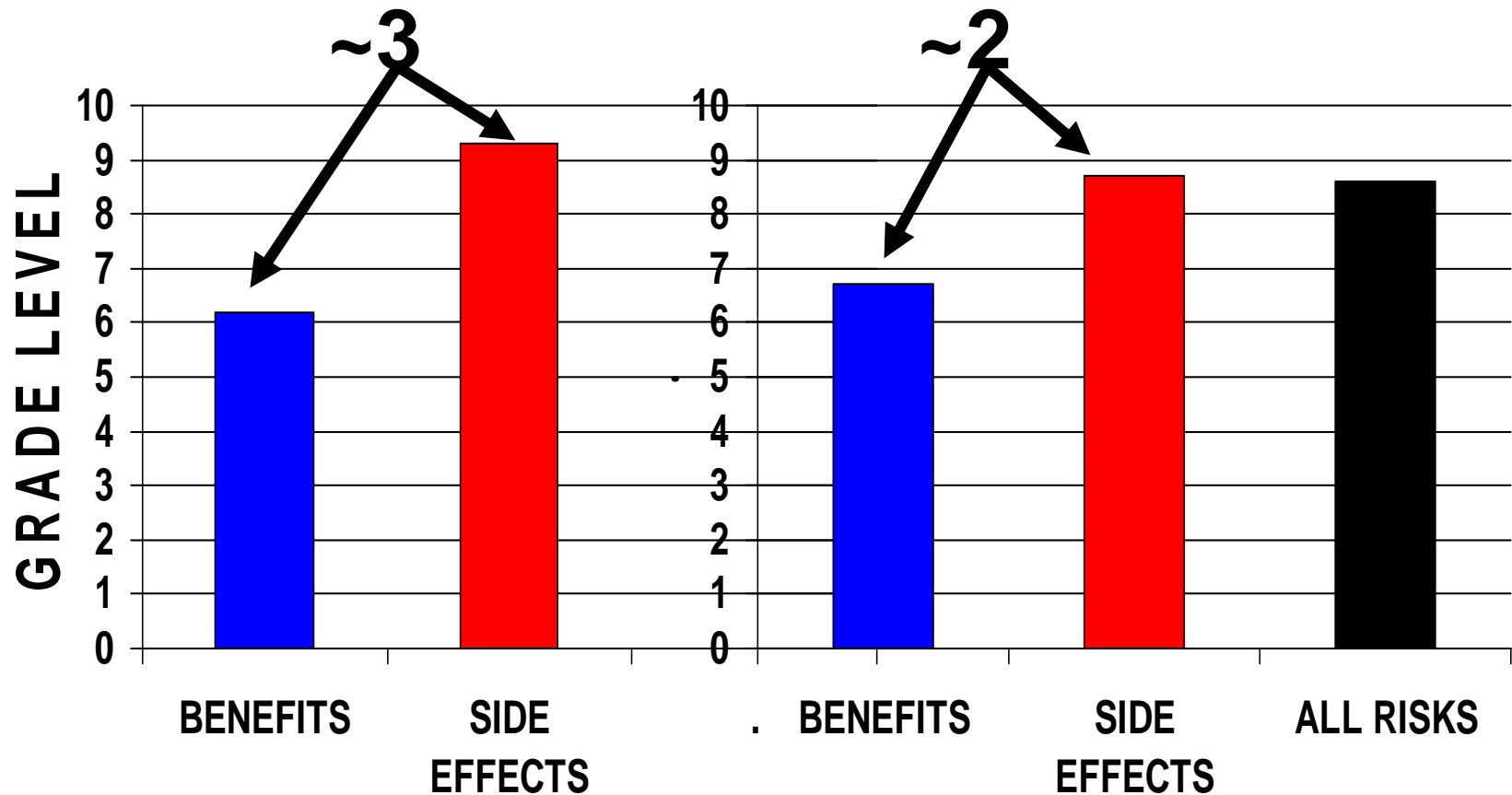


Averages

READABILITY

2001

2005



Each Rx

READABILITY

Difference Score (B - SE)

READABILITY

Difference Score (B - SE)

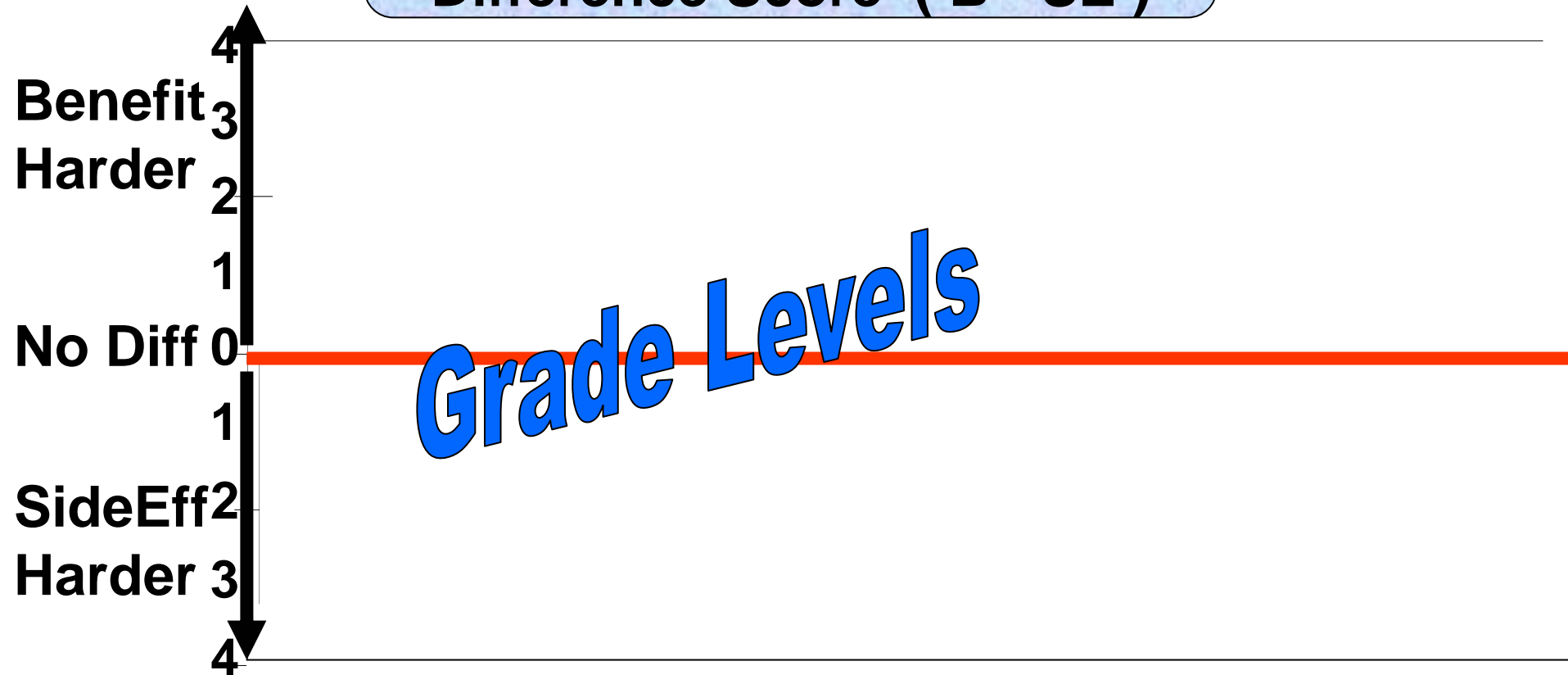
**Benefit
Harder**

No Diff

**SideEff
Harder**

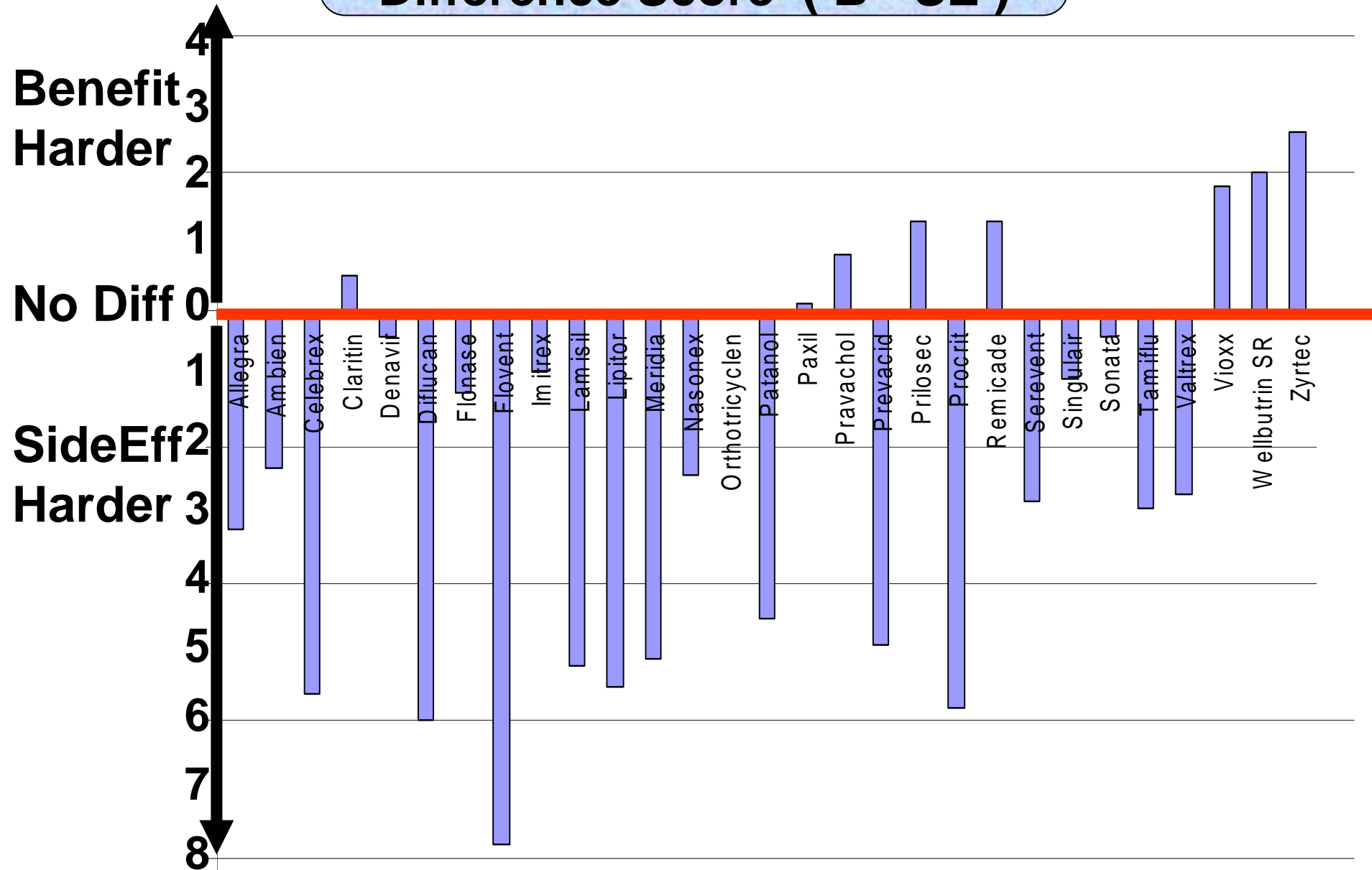
READABILITY

Difference Score (B - SE)



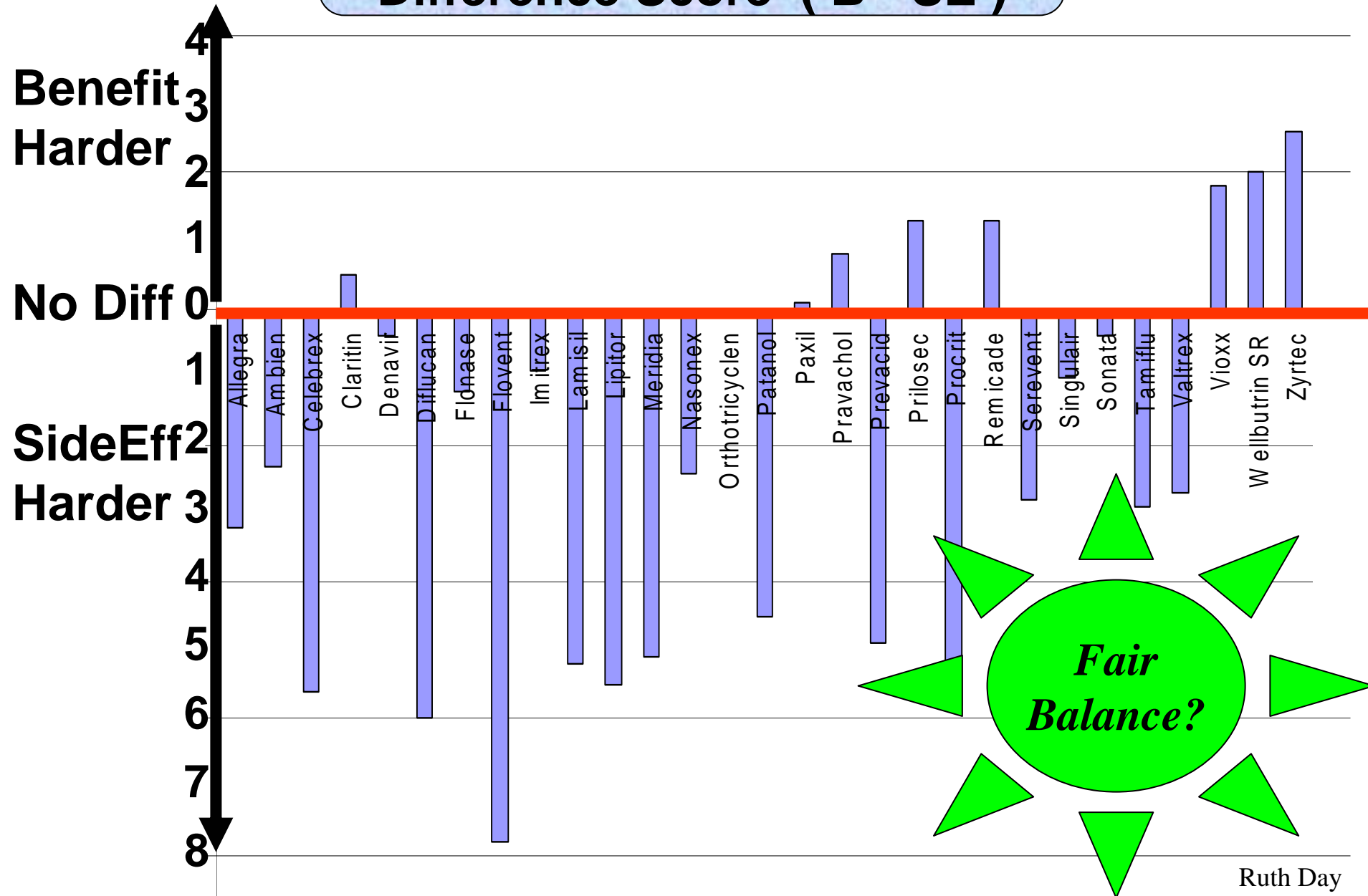
READABILITY

Difference Score (B - SE)



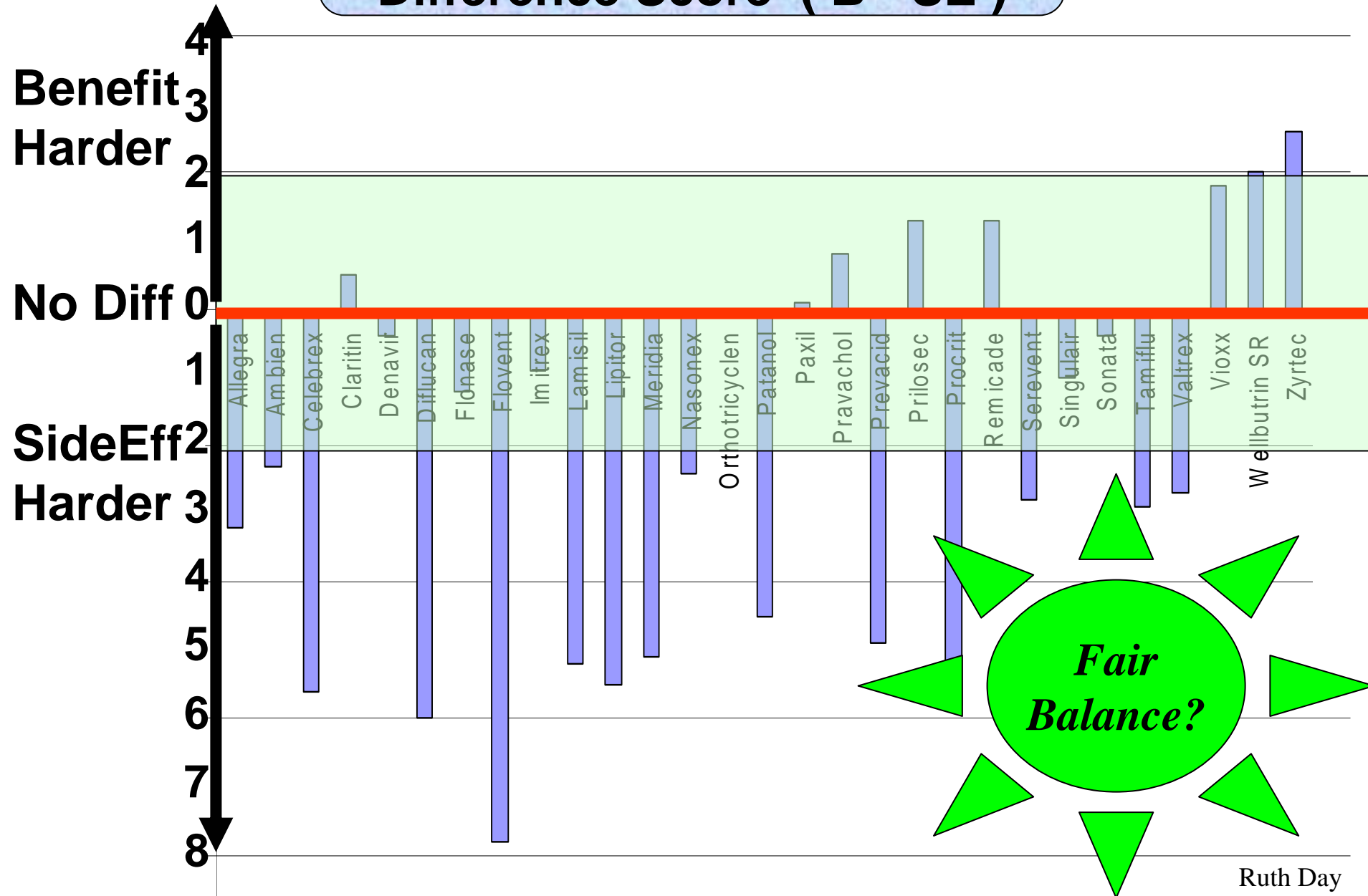
READABILITY

Difference Score (B - SE)



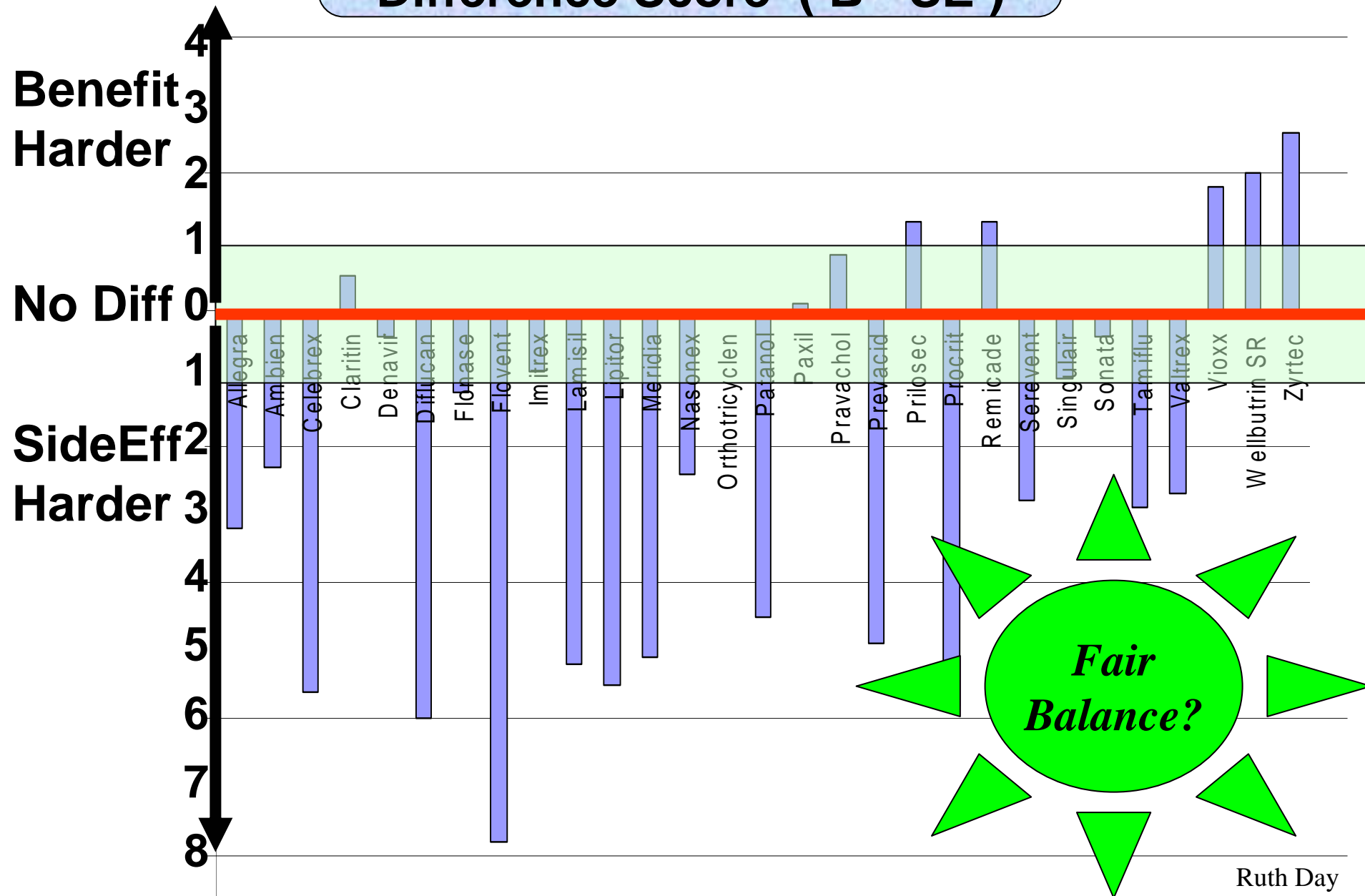
READABILITY

Difference Score (B - SE)



READABILITY

Difference Score (B - SE)



LOCATION of INFORMATION

SPEAKER TIMELINE



TIME (sec)

SPEAKER TIMELINE

Allegra



SPEAKER TIMELINE

Allegra



It's allergy season
or Allegra season.

SPEAKER TIMELINE

Allegra



It's allergy season
or Allegra season.

Enjoy your world with non-drowsy
Allegra for people 12 and over.

SPEAKER TIMELINE

Allegra



It's allergy season
or Allegra season.

Enjoy your world with non-drowsy
Allegra for people 12 and over.

In clinical studies, less than 3% of people experienced drowsiness, cold or flu, nausea, or menstrual pain. Ask your doctor for more information about Allegra. And turn this allergy season into Allegra season. Enjoy your world.

SPEAKER TIMELINE

Allegra

Chunking



It's allergy season
or Allegra season.

Enjoy your world with non-drowsy
Allegra for people 12 and over.

No Chunking

In clinical studies, less than 3% of people experienced drowsiness, cold or flu, nausea, or menstrual pain. Ask your doctor for more information about Allegra. And turn this allergy season into Allegra season. Enjoy your world.

COGNITIVE PRINCIPLE

COGNITIVE PRINCIPLE:

Serial Position Effect

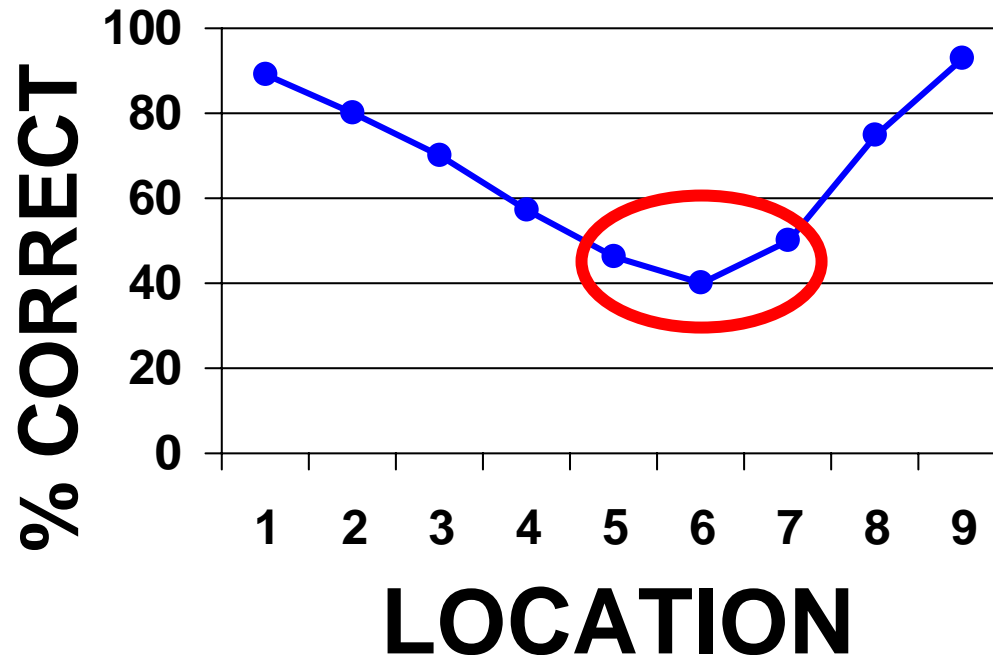
Task: --see/hear list of items
--report them

COGNITIVE PRINCIPLE:

Serial Position Effect

Task: --see/hear list of items
--report them

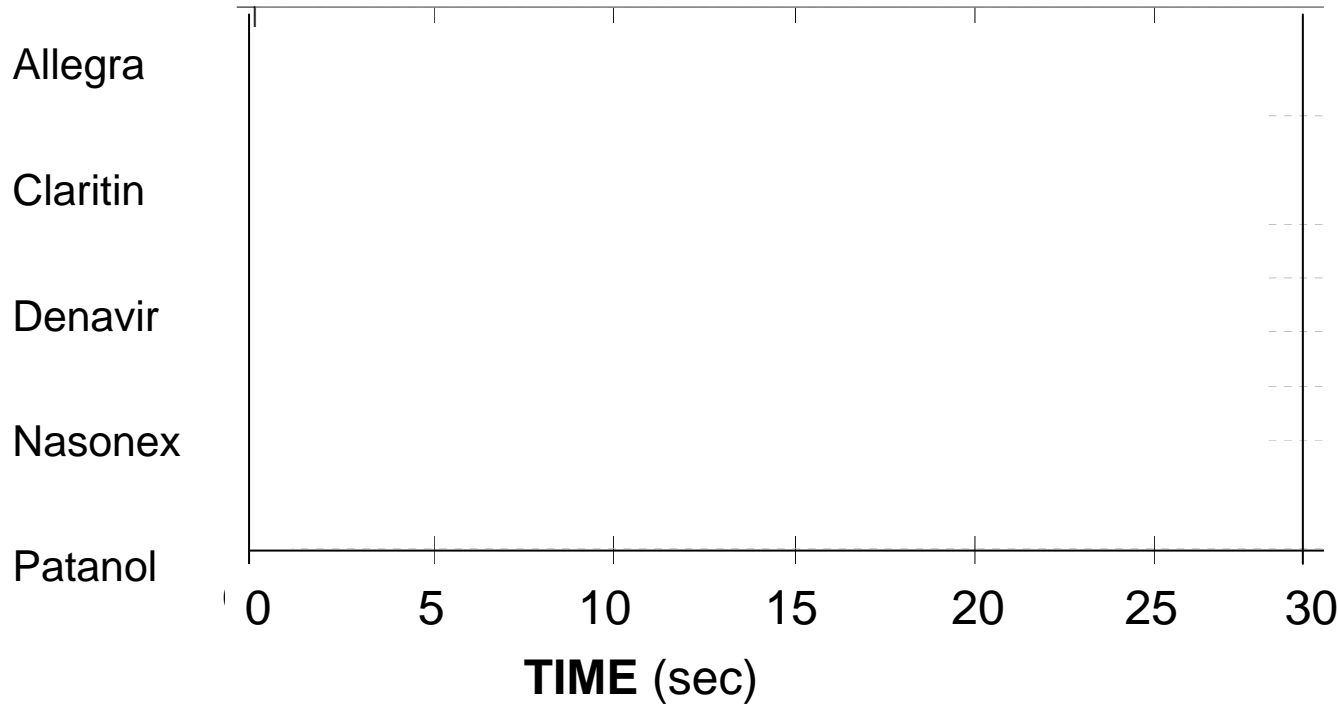
Typical Results:



2001

Location of Side Effects

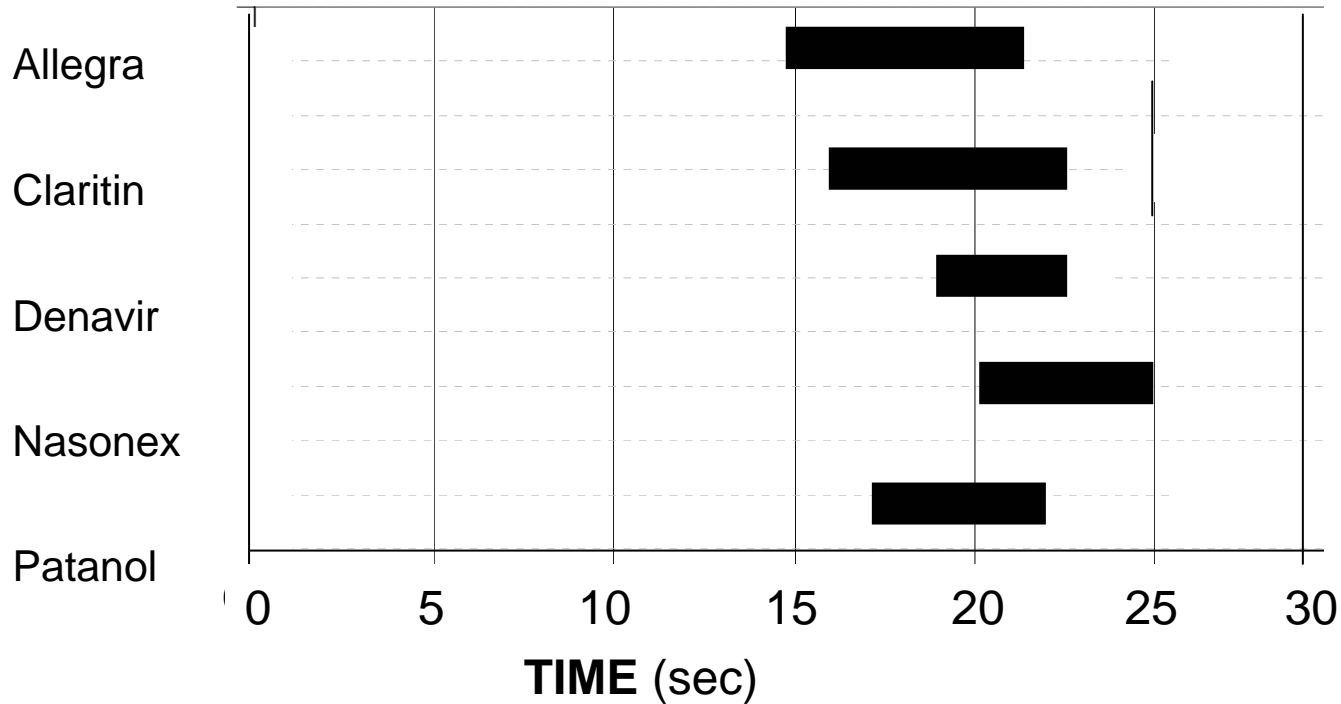
30-sec. Ads



2001

Location of Side Effects

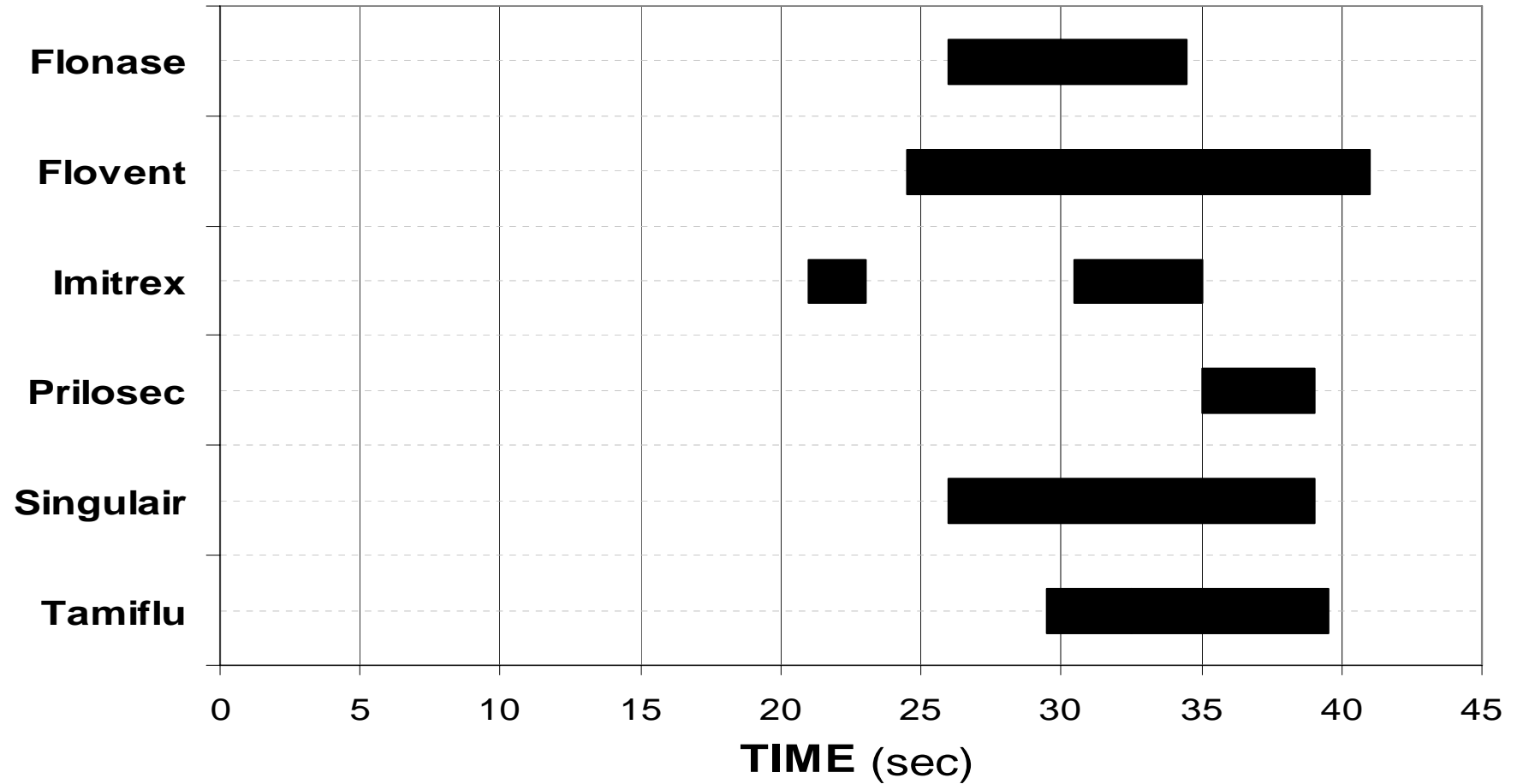
30-sec. Ads



2001

Location of Side Effects

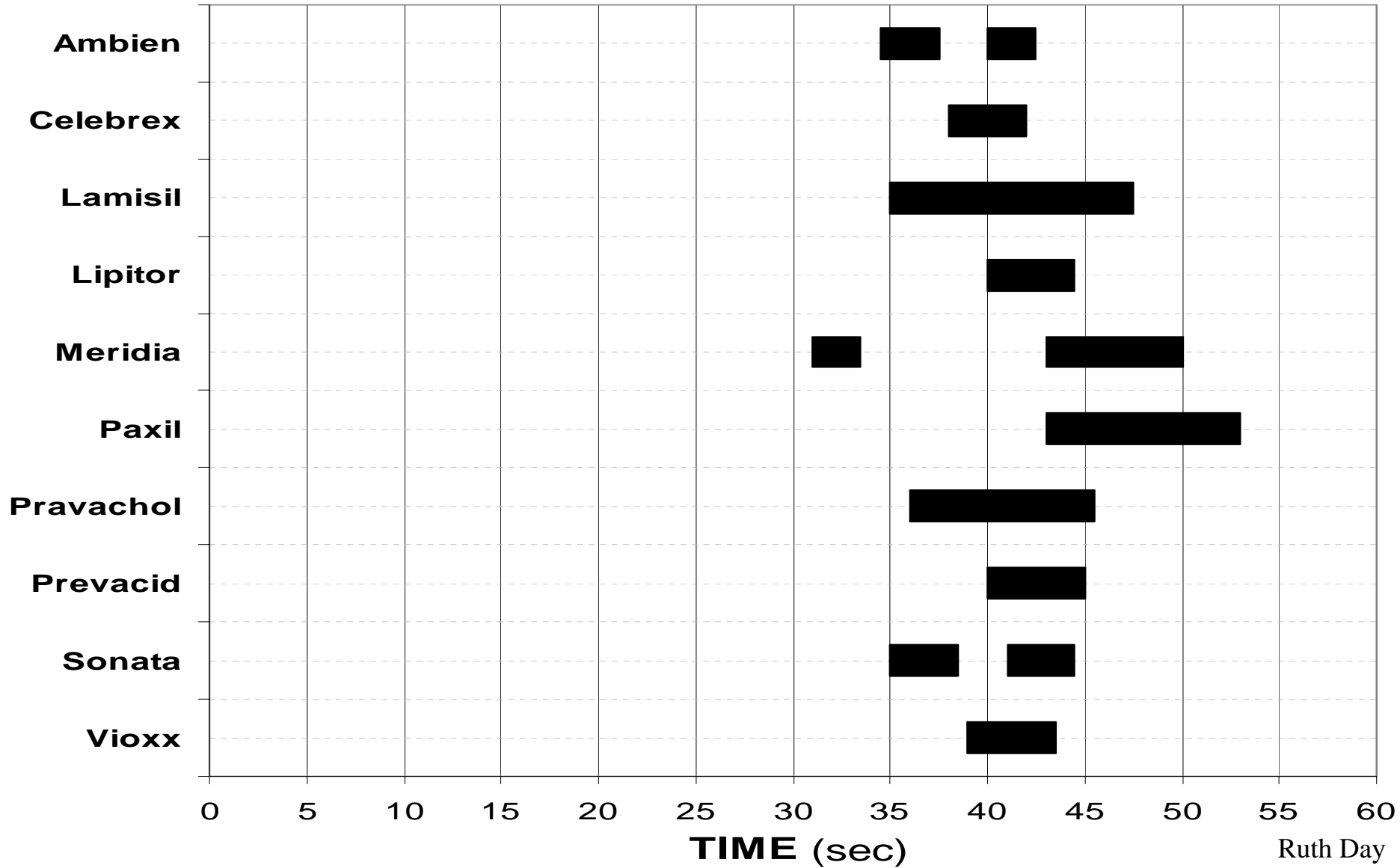
45-sec. Ads



2001

Location of Side Effects

60-sec. Ads



Location of Side Effects

**Unfavorable
location**

Location of Side Effects

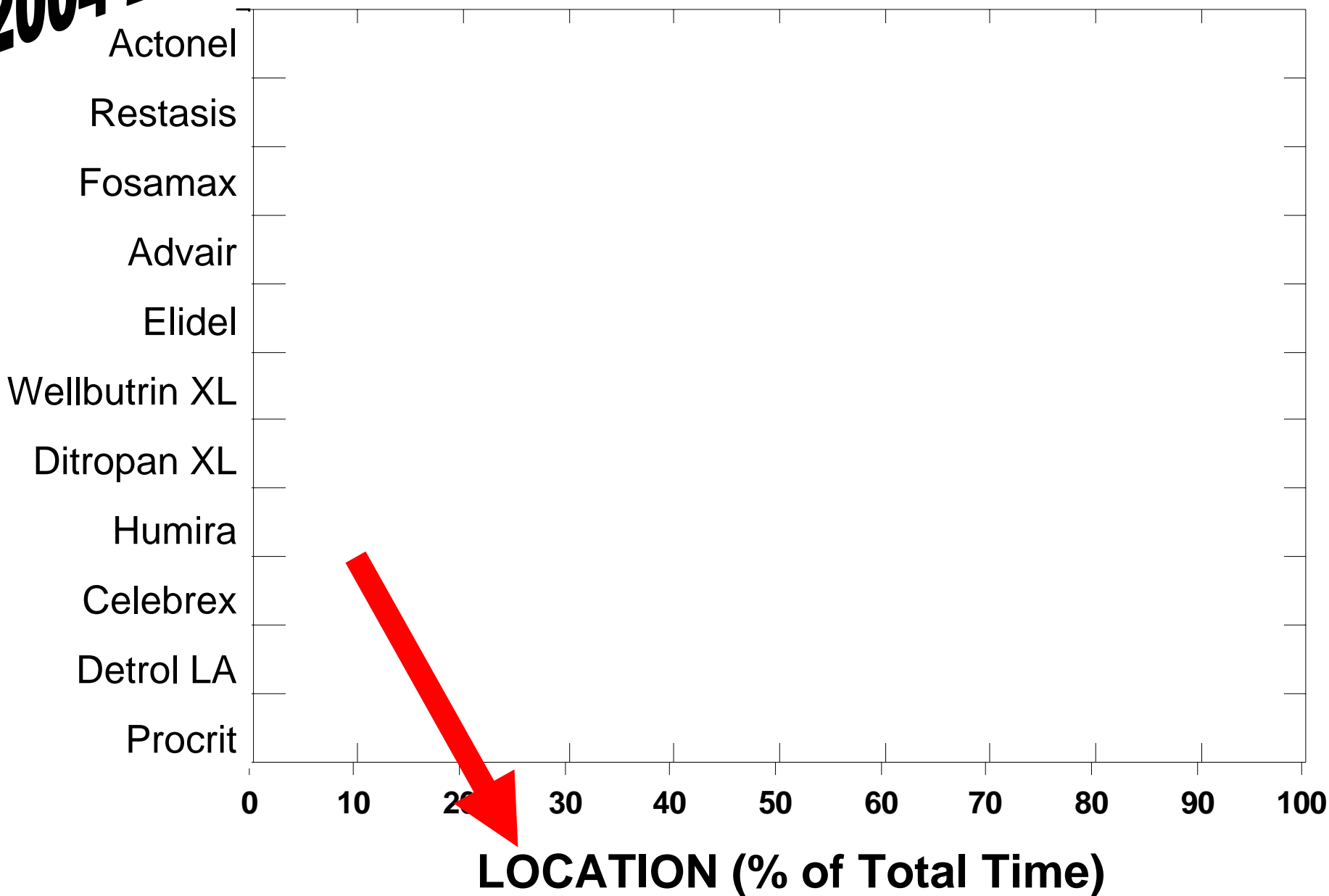
2000-2001

2005



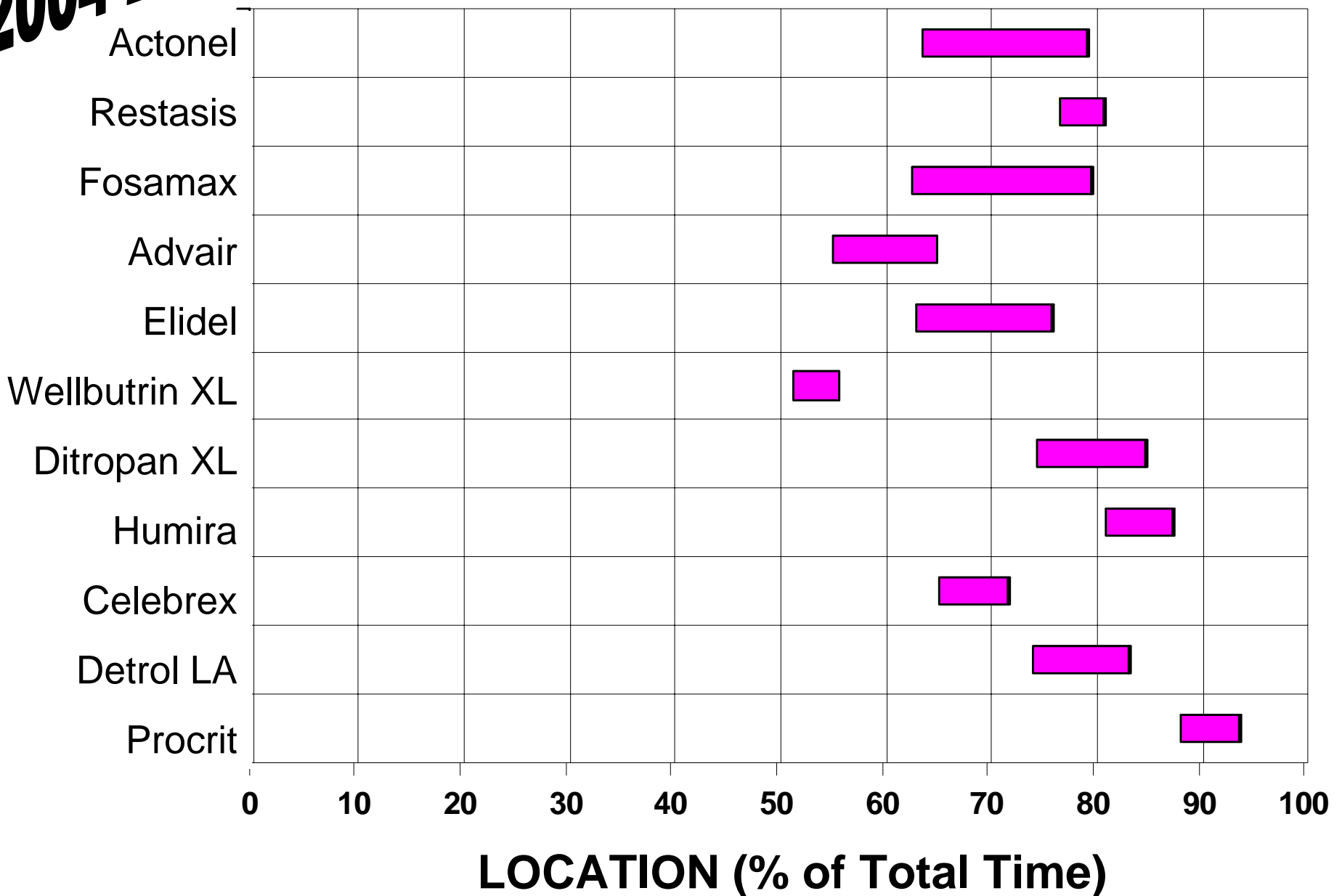
2004-2005

Location of Side Effects



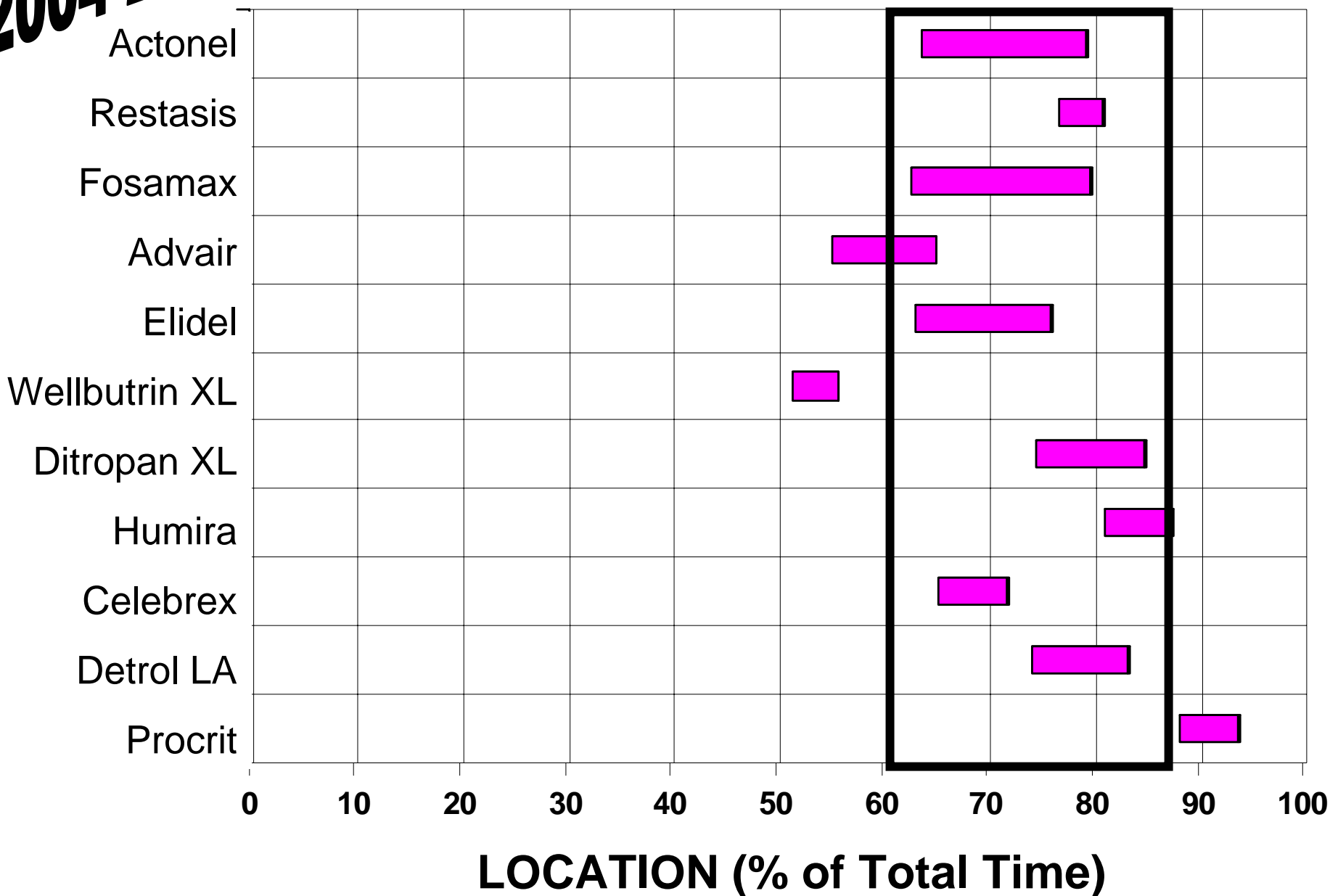
2004-2005

Location of Side Effects



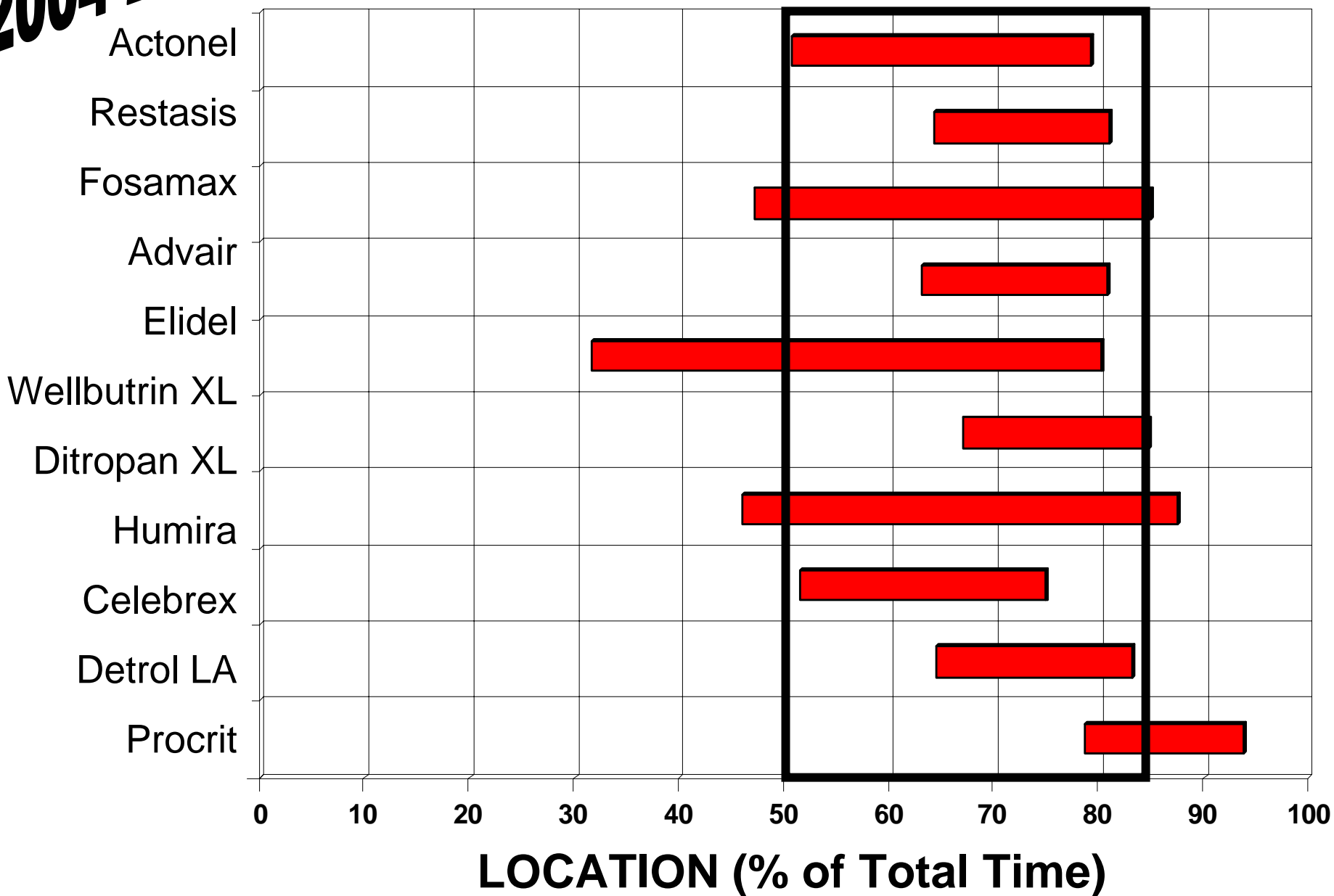
2004-2005

Location of Side Effects



2004-2005

Location of **Risks**



Location of Risks

Unfavorable!

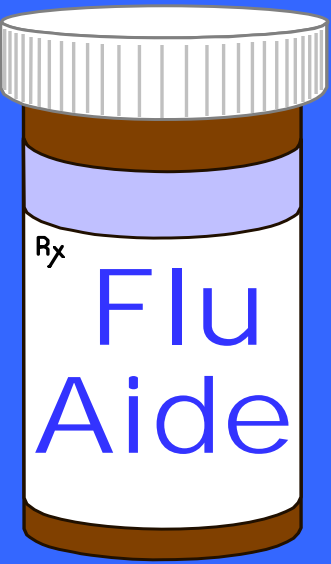
Location of Risks

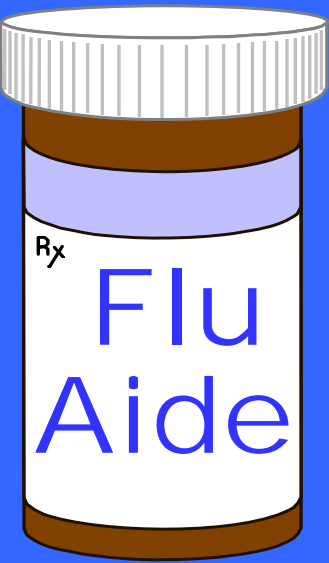
Unfavorable!

But

- What effect does location have on cognition?
- Need evidence

Experimental TV Ad Hypothetical Drug





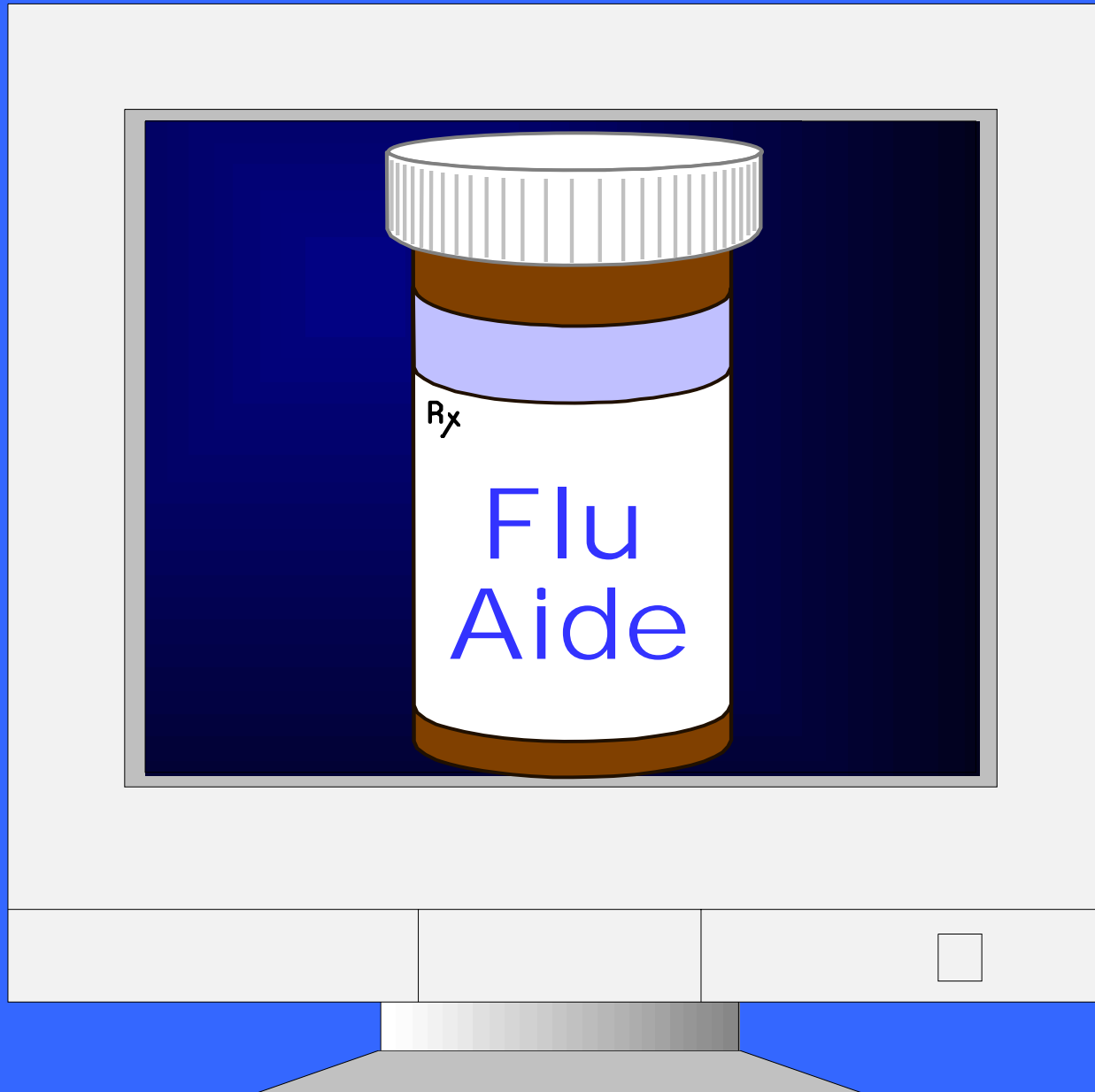
Experimental TV Ad

Hypothetical Drug

Structure & content

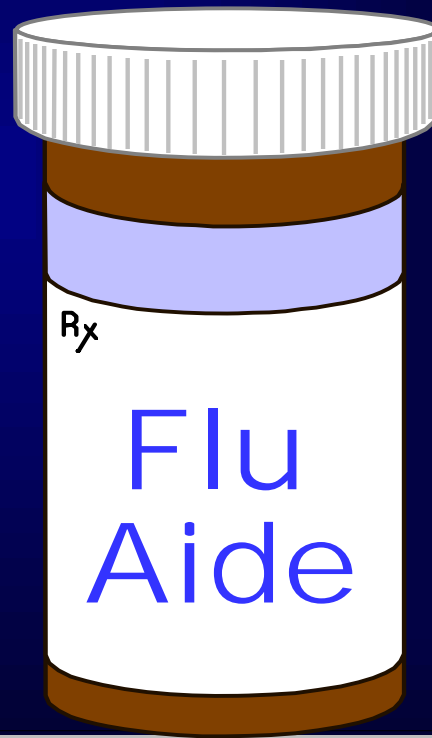
- Like typical ads
- Purpose
 - vary specific factors
 - observe effects on cognition

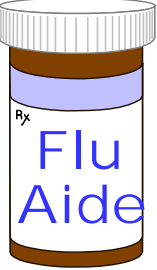
Experiment



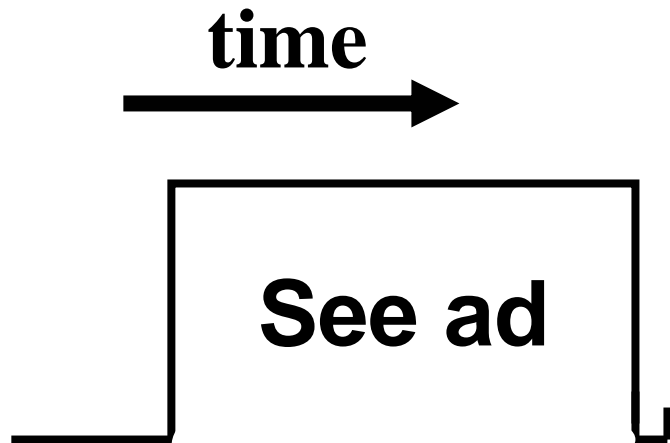
Experiment

**What were
the side
effects?**





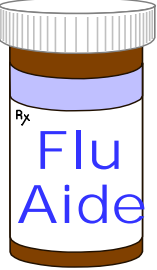
Experiment



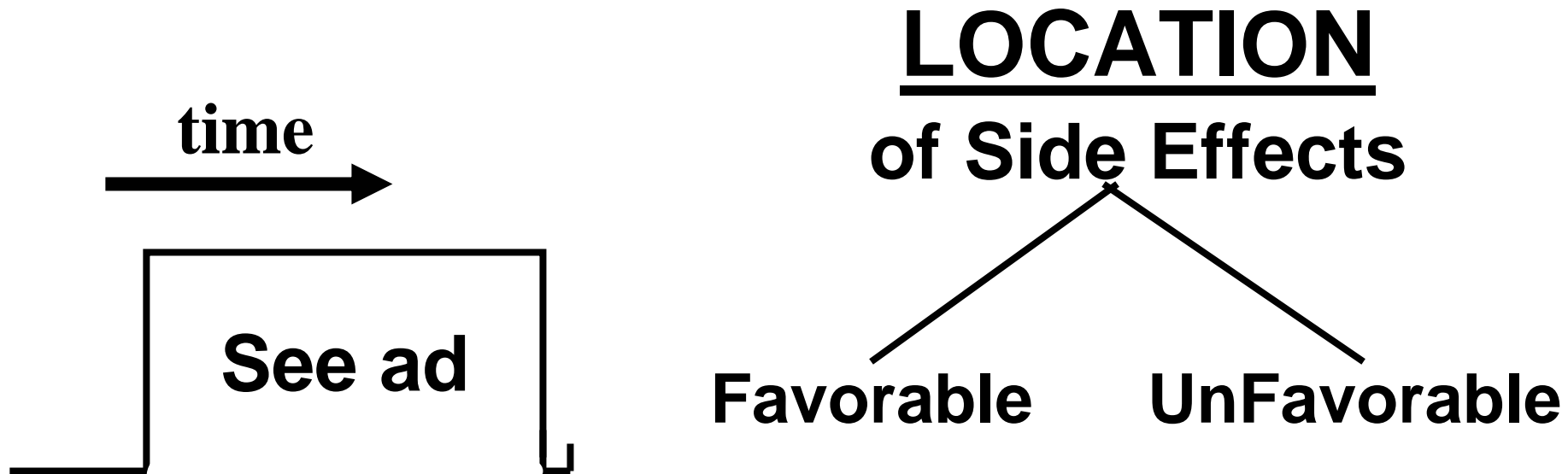
LOCATION of Side Effects

Favorable

UnFavorable

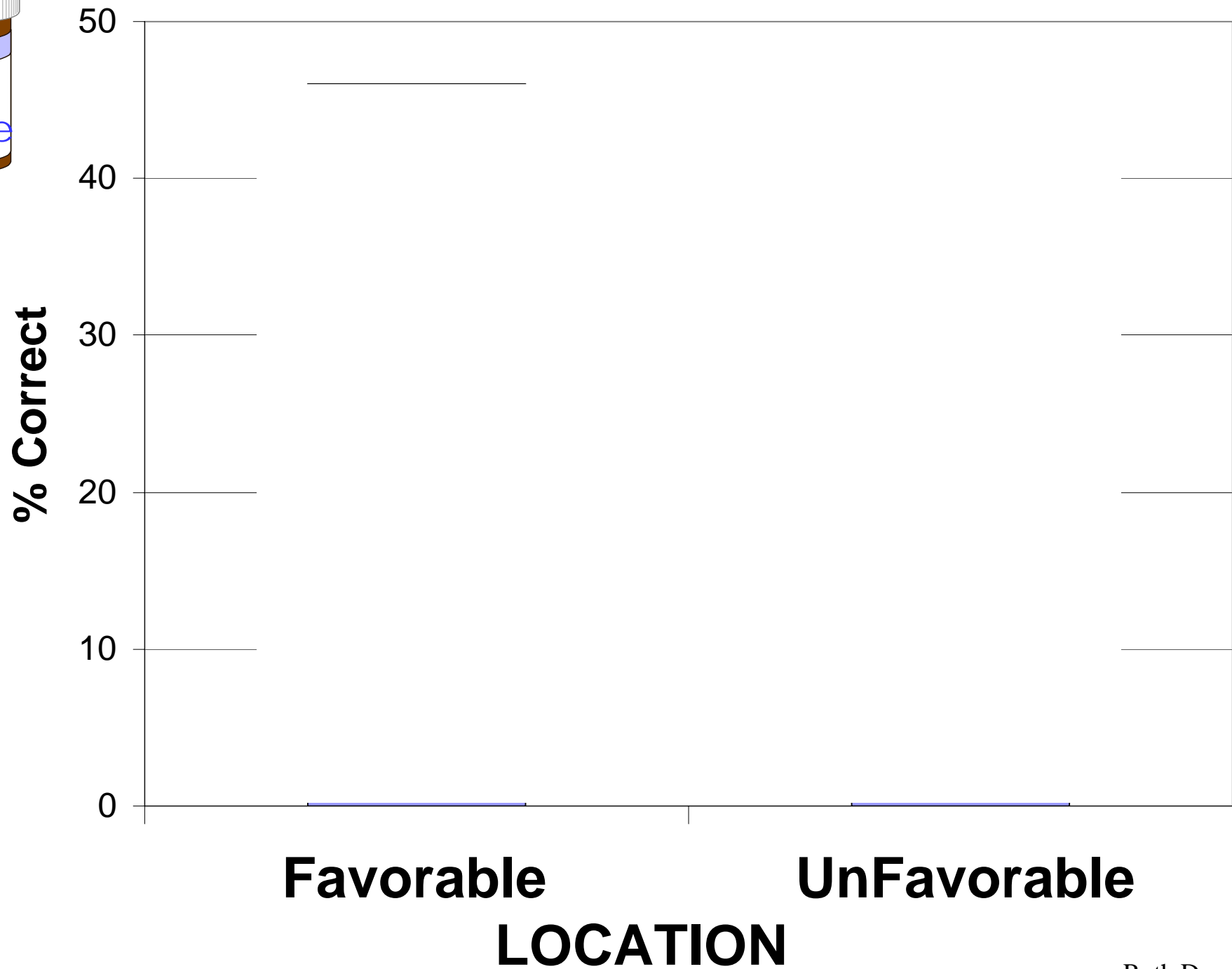
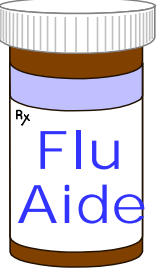


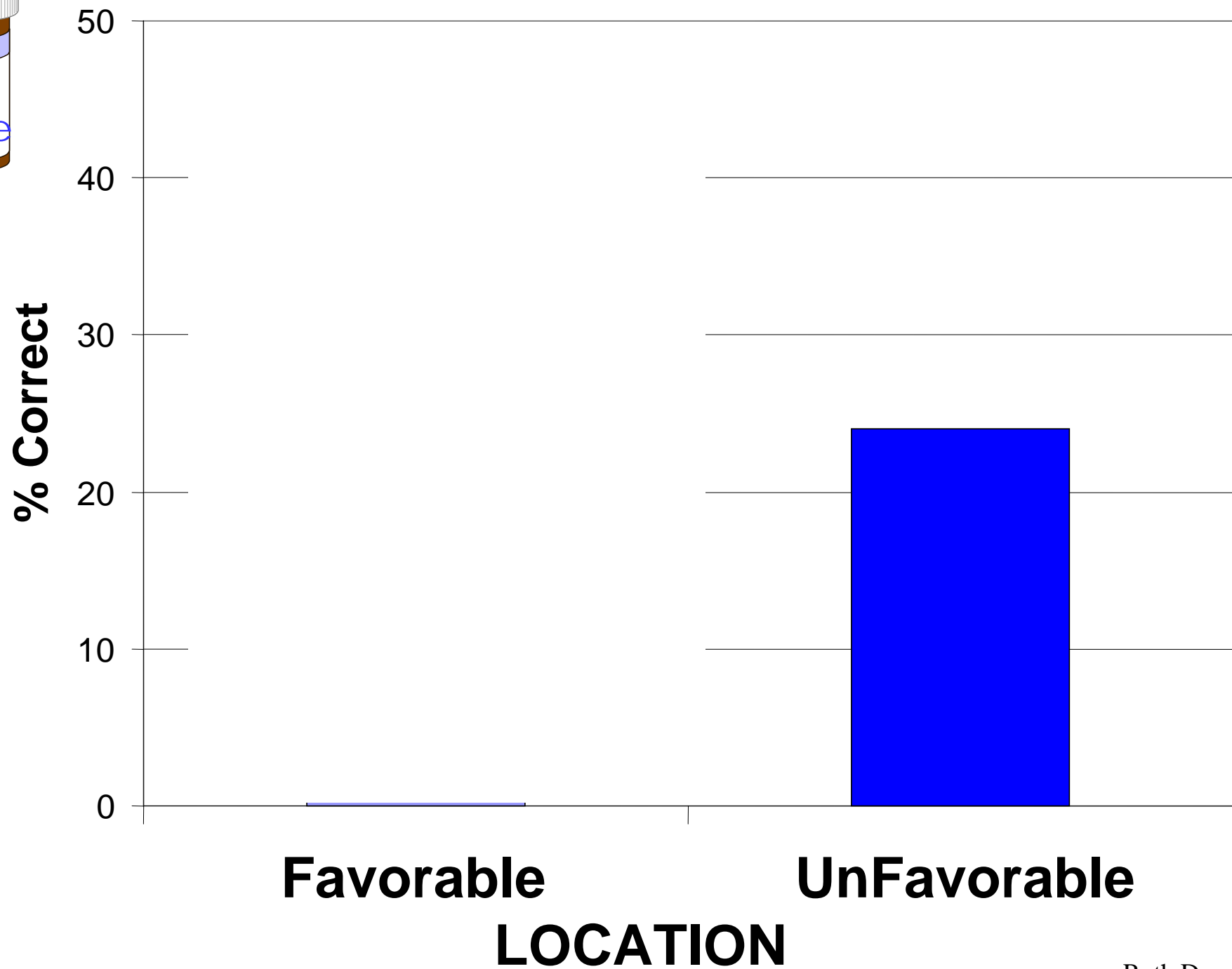
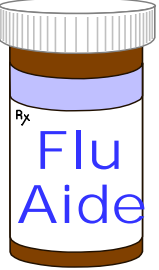
Experiment

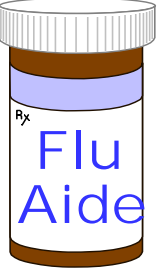


Same visual
Same auditory

Differ only in location of side effects







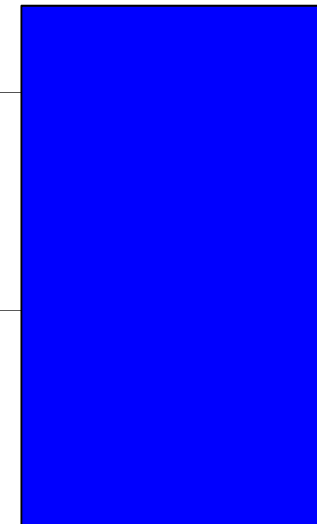
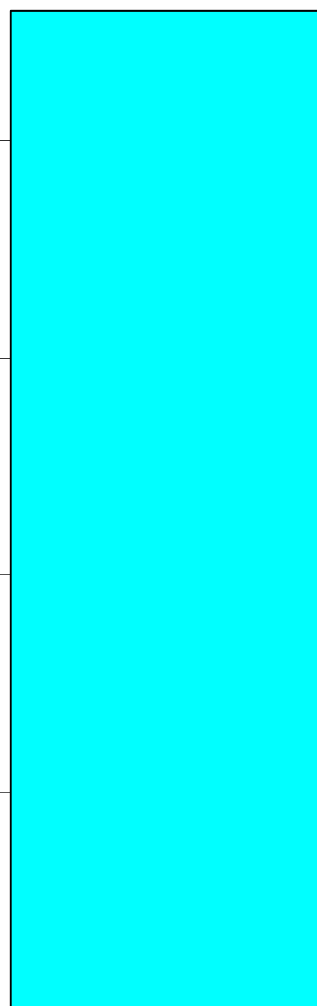
% Correct

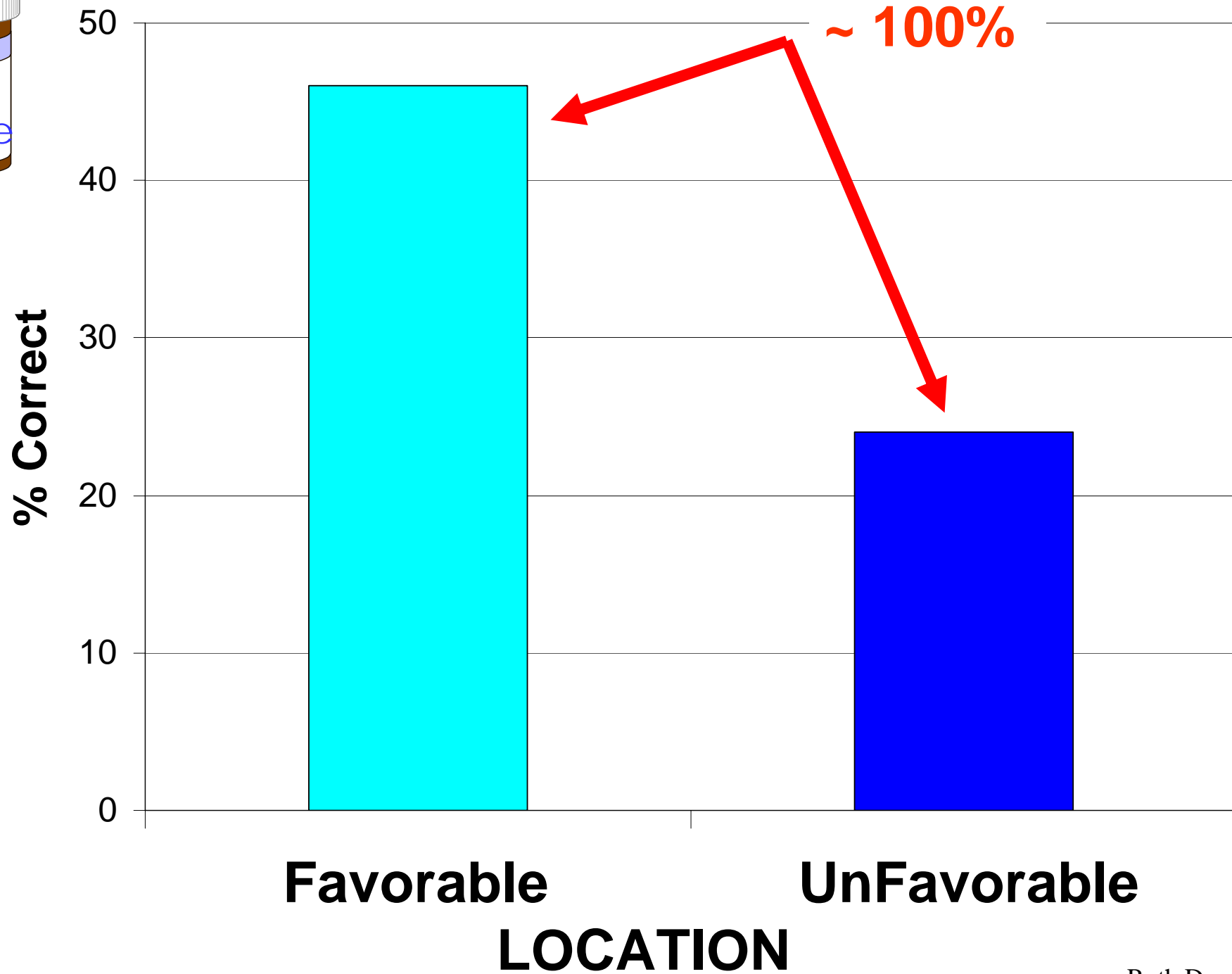
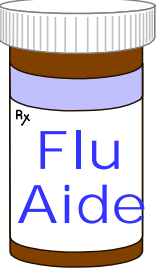
50
40
30
20
10
0

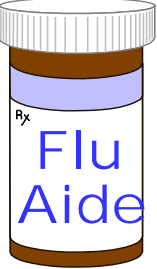
Favorable

UnFavorable

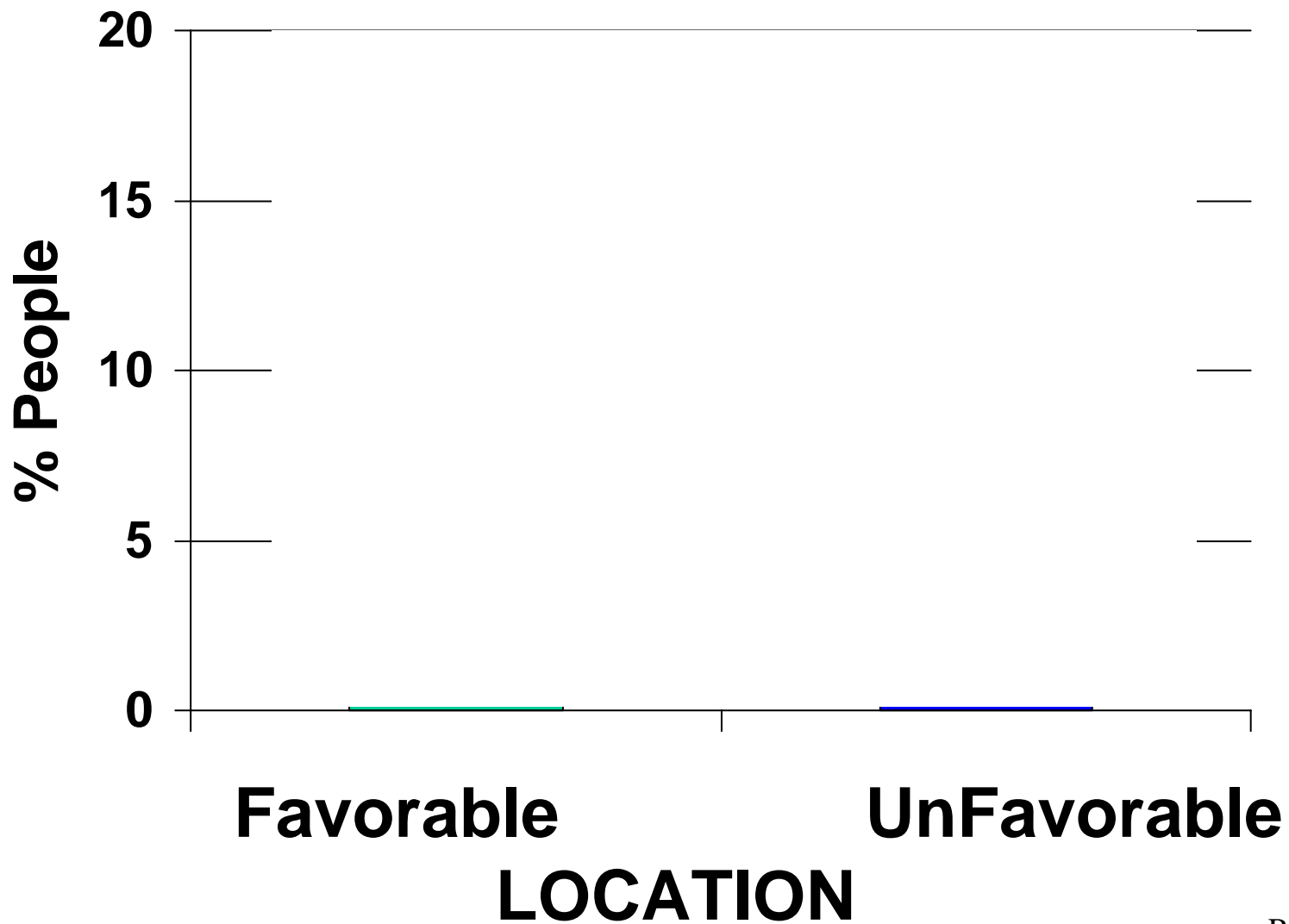
LOCATION

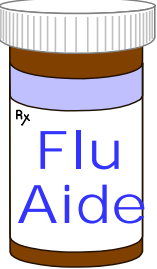




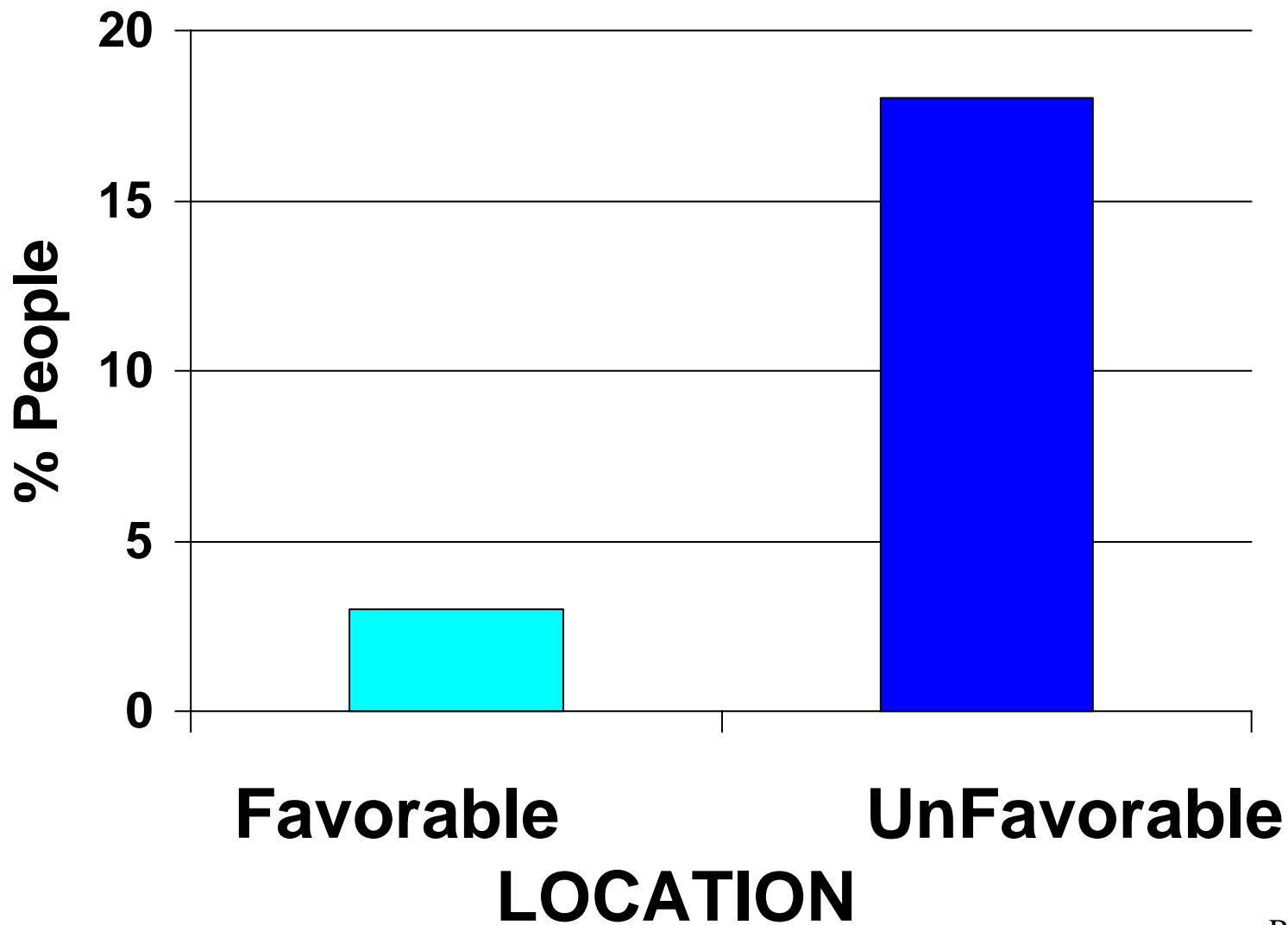


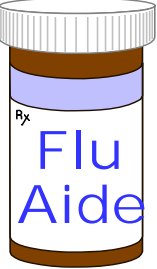
Unable to Report Any Side Effects



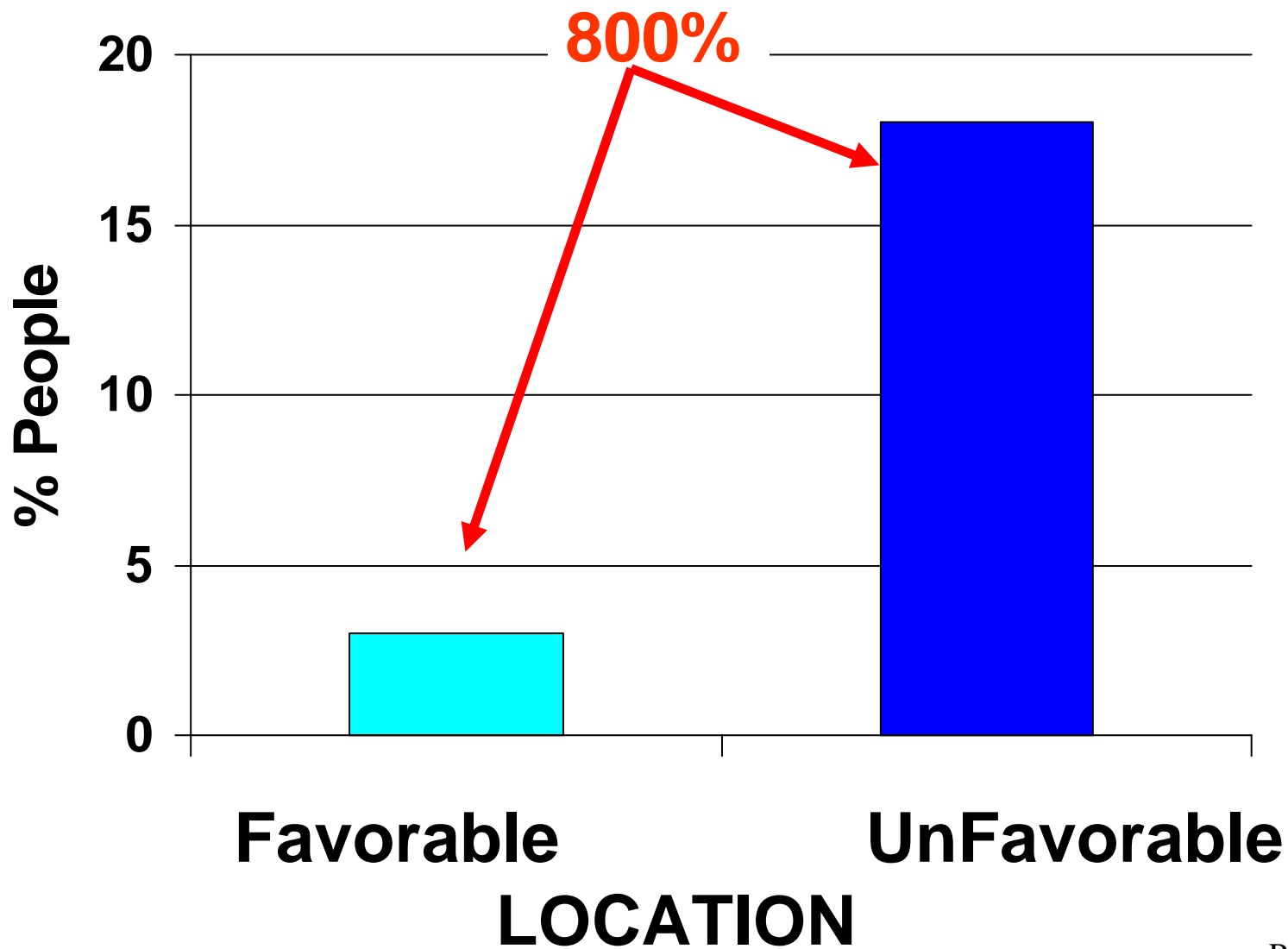


Unable to Report Any Side Effects



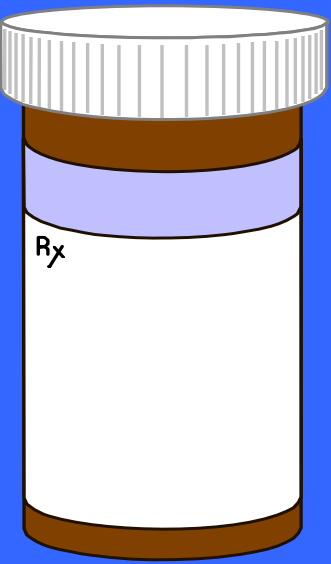


Unable to Report Any Side Effects



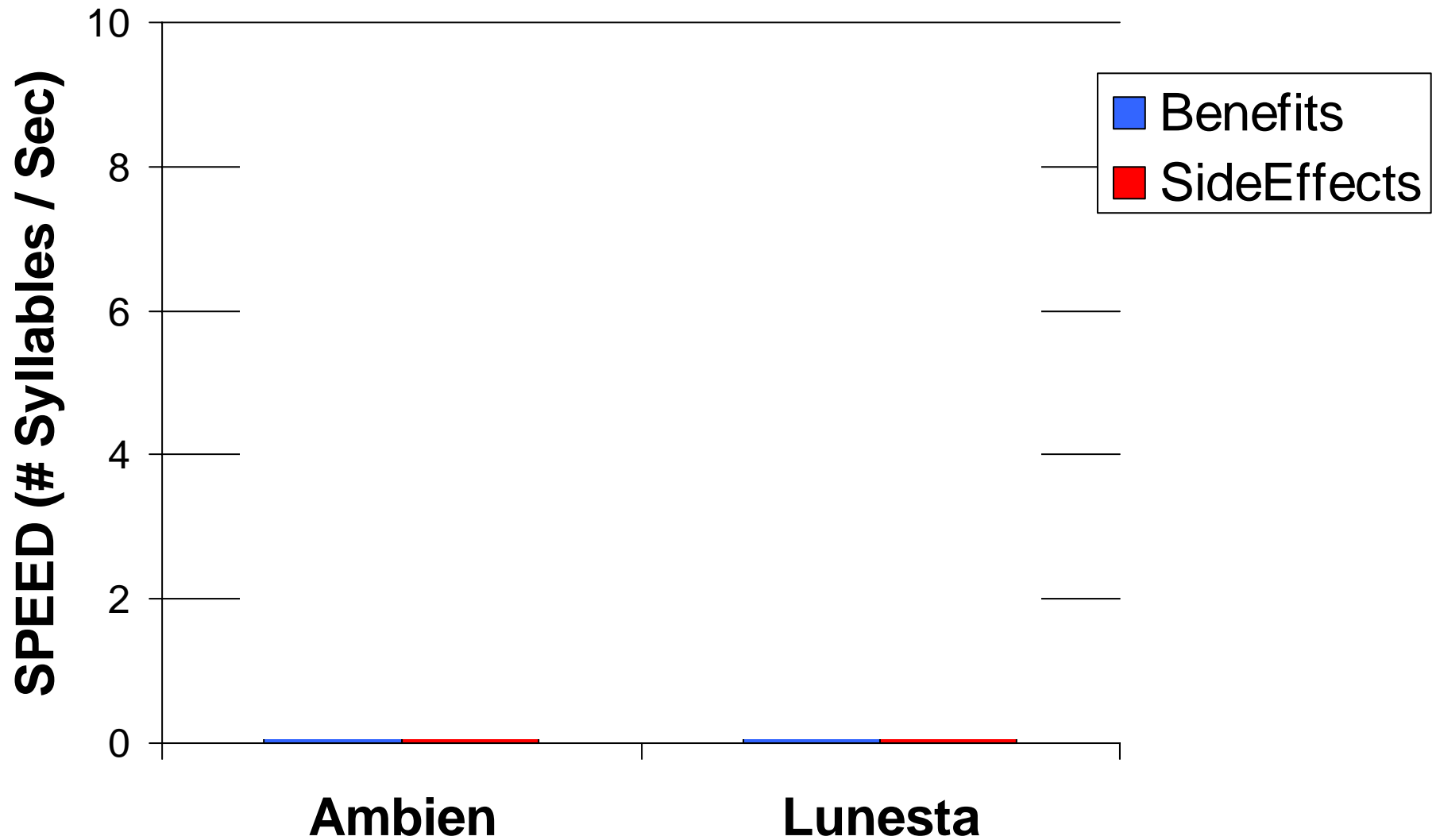
Actual TV Ads

Specific Factors

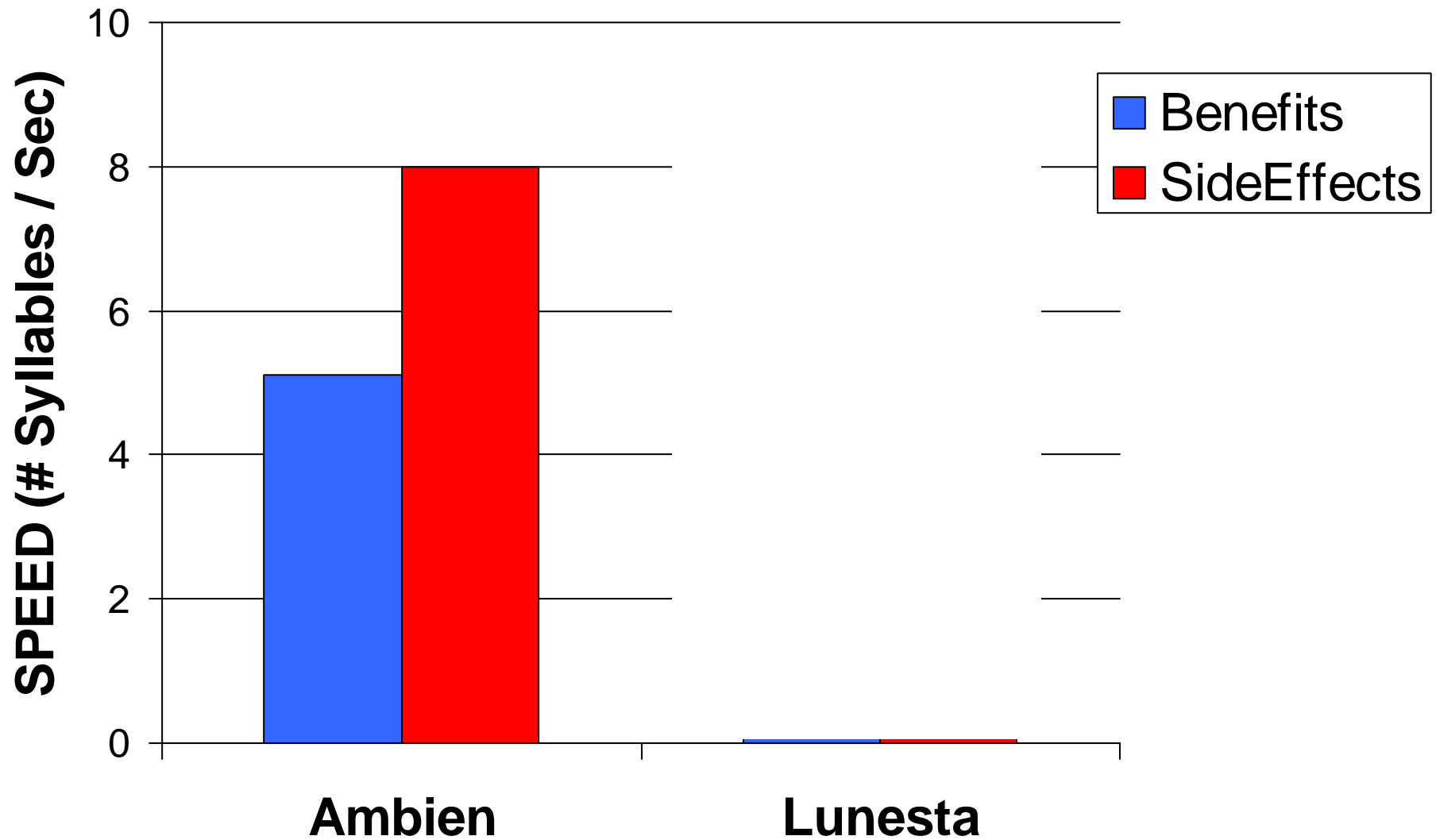


Speed

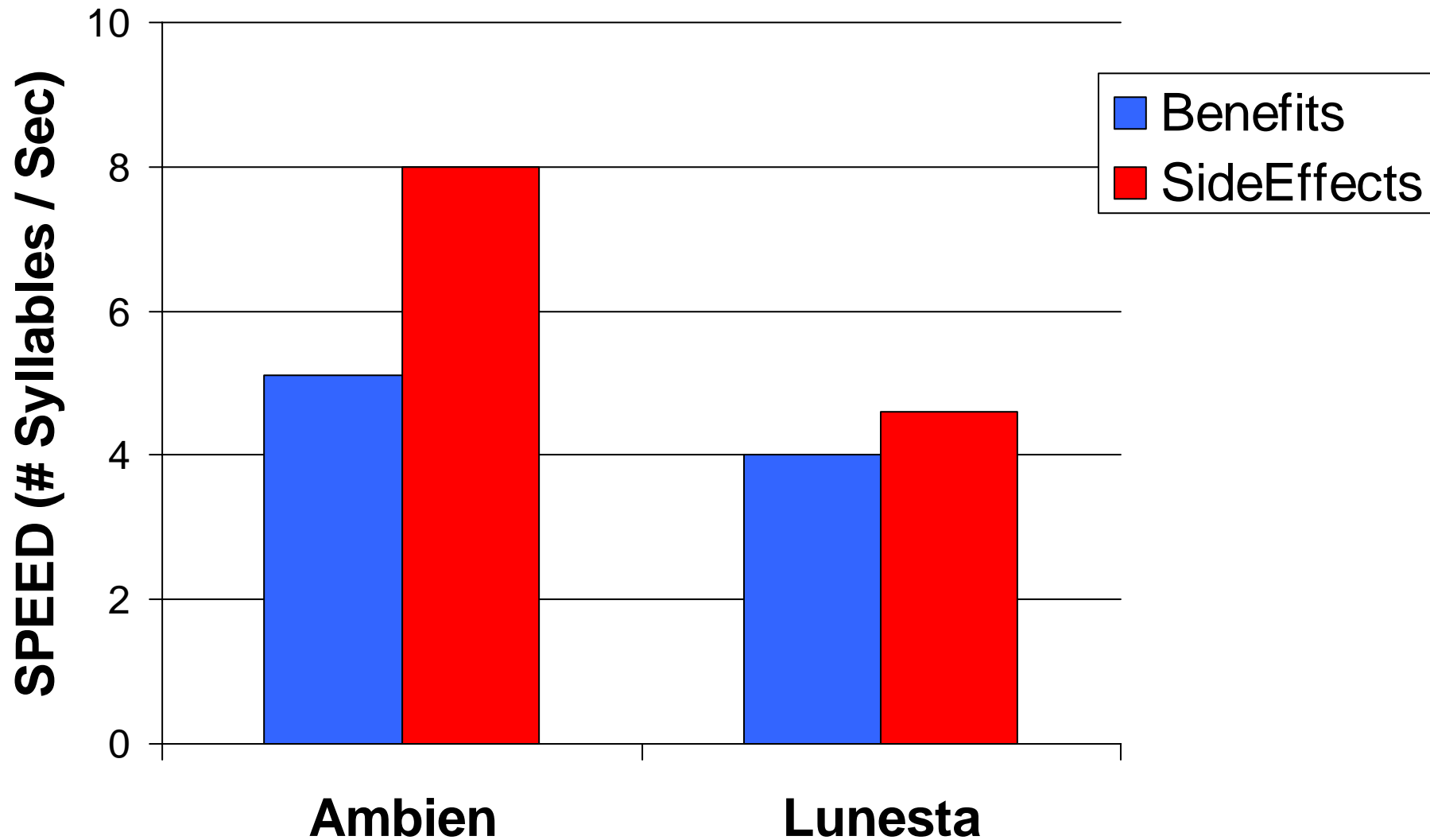
Speed



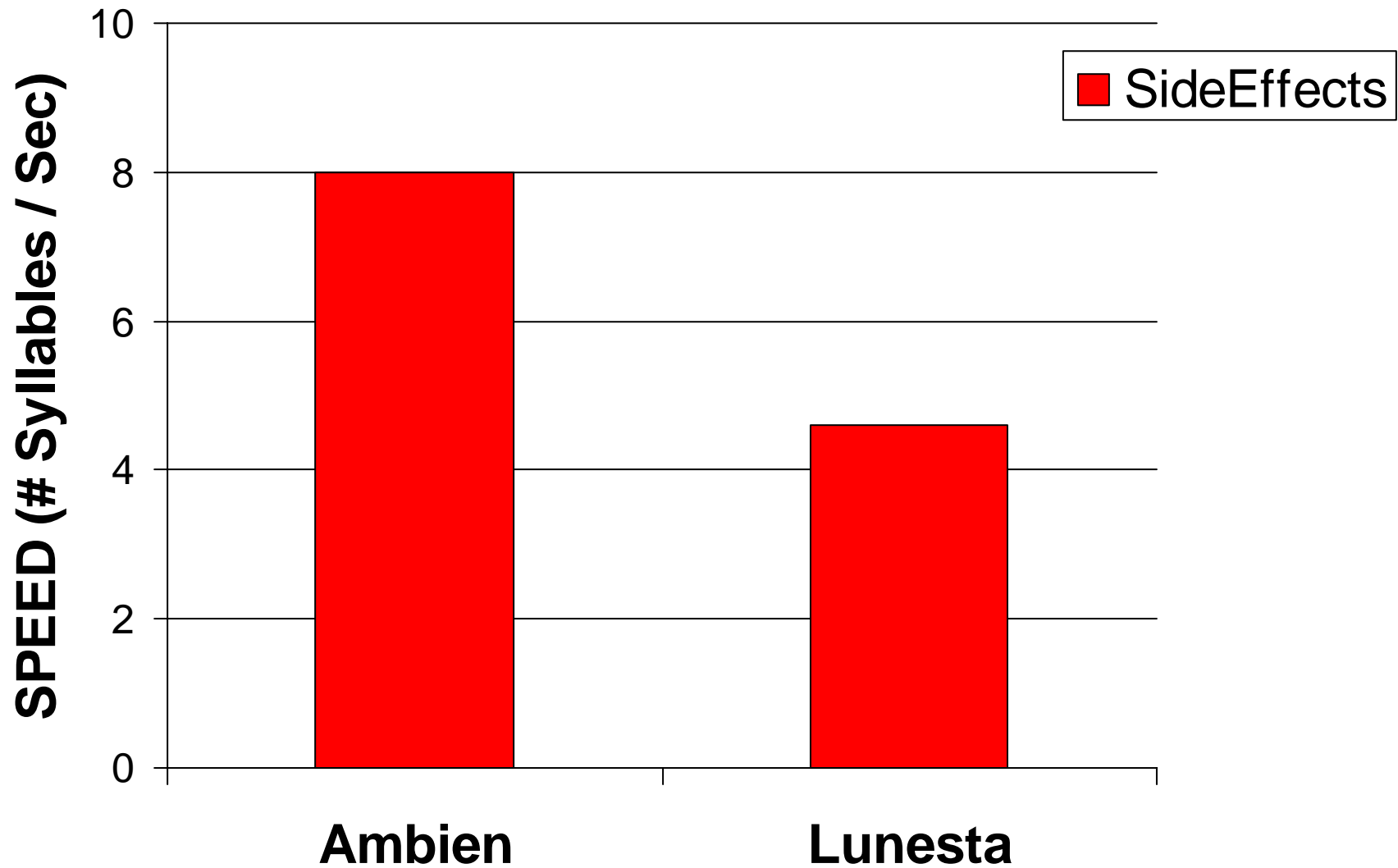
Speed



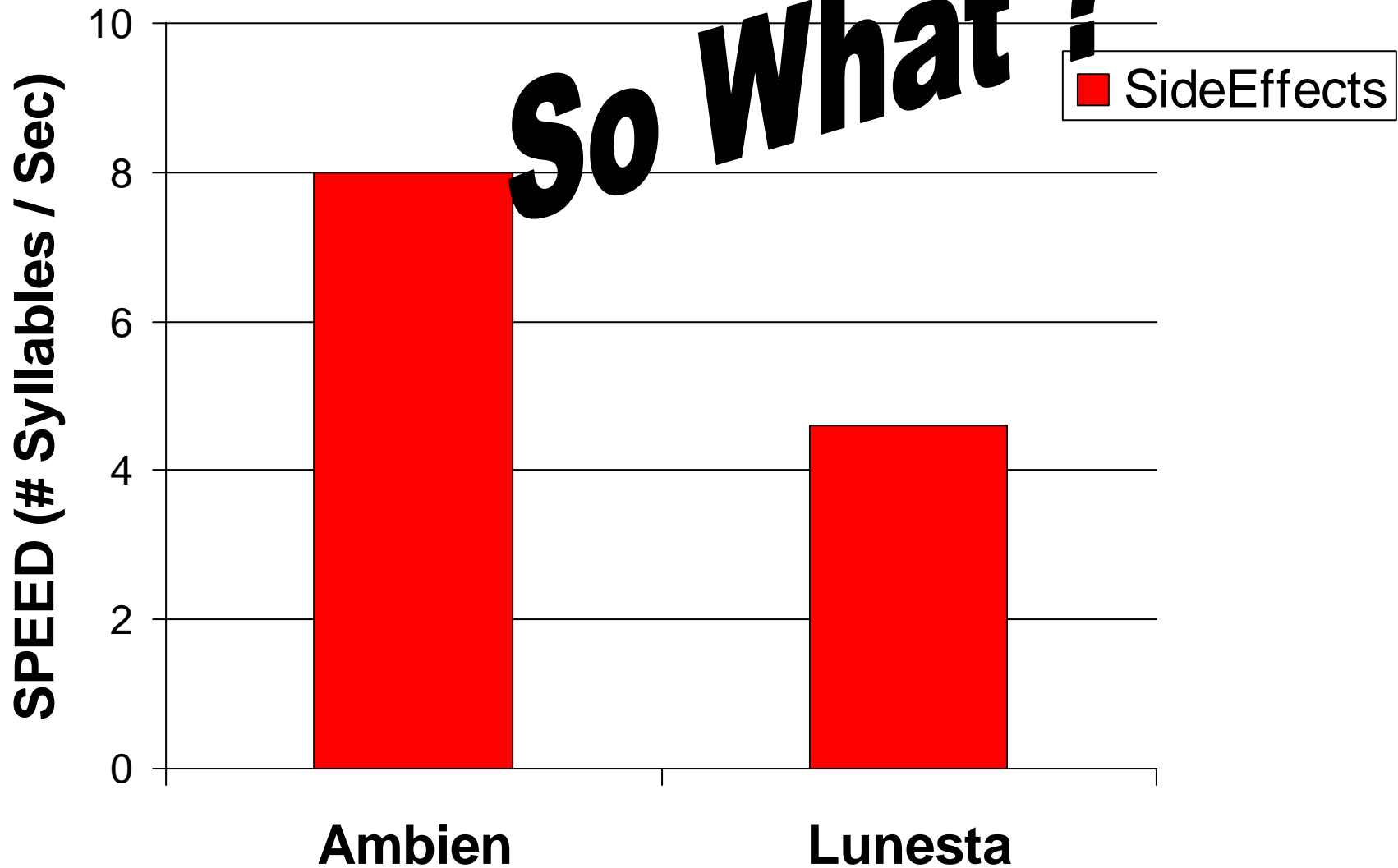
Speed



Speed



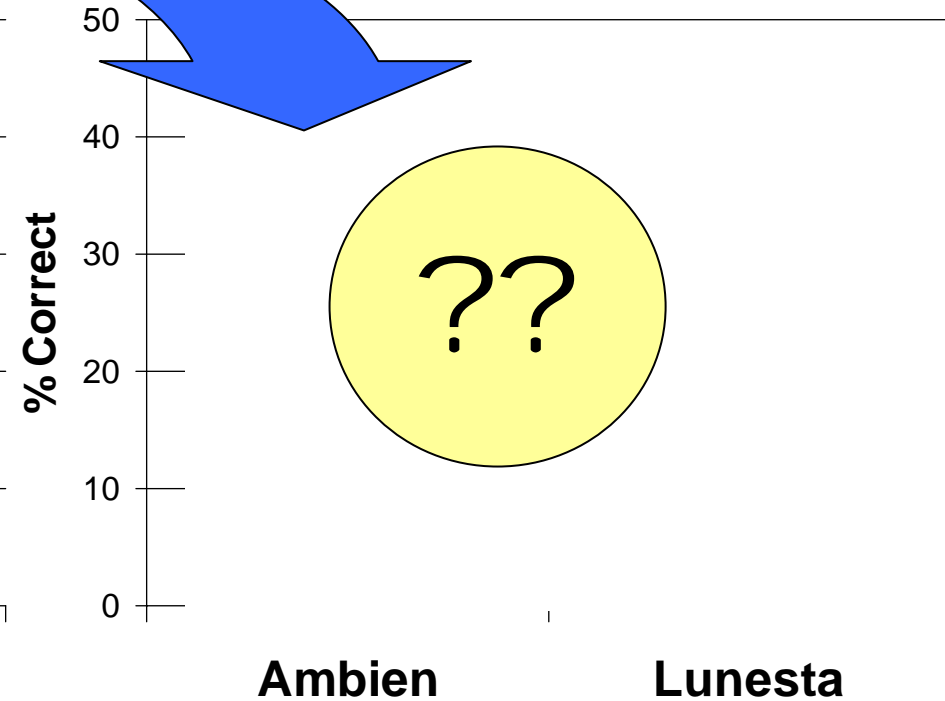
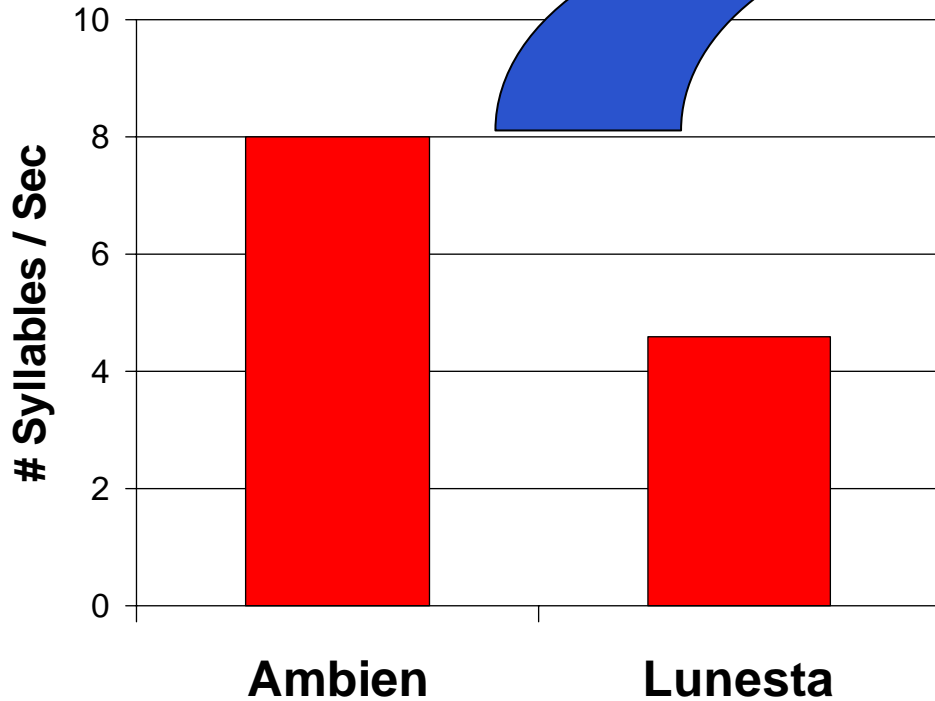
Speed



Speed

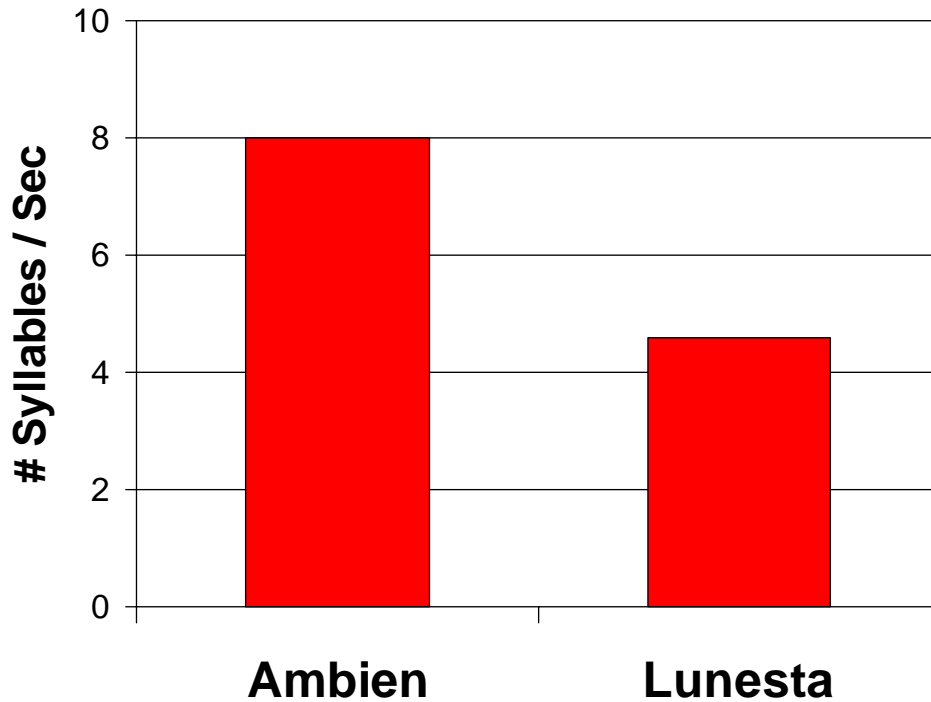
SPEED

ACCURACY

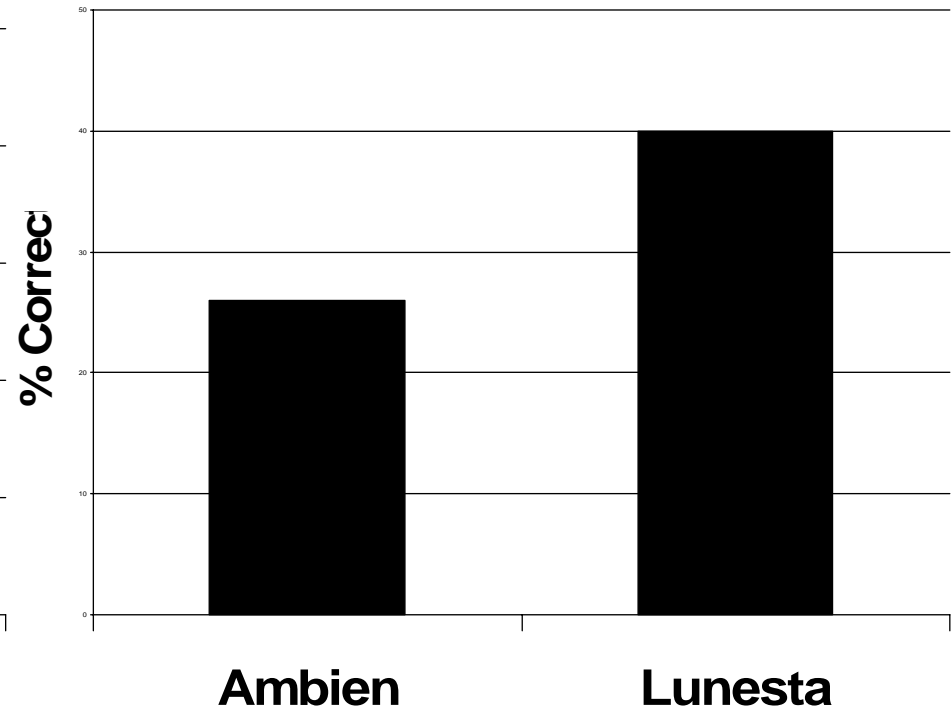


Speed

SPEED



ACCURACY



Divided Attention

Divided Attention

Nasonex



Nasonex: Side Effects











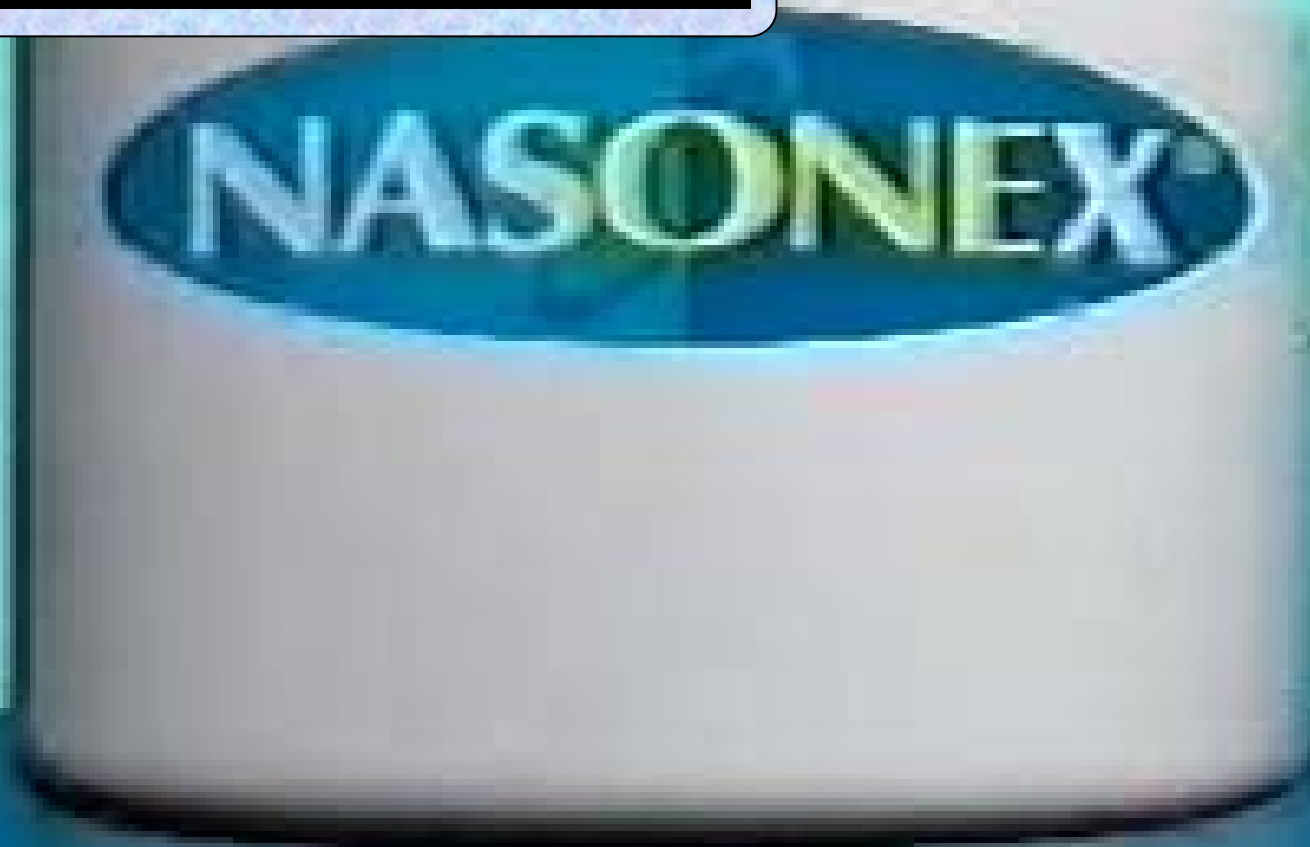








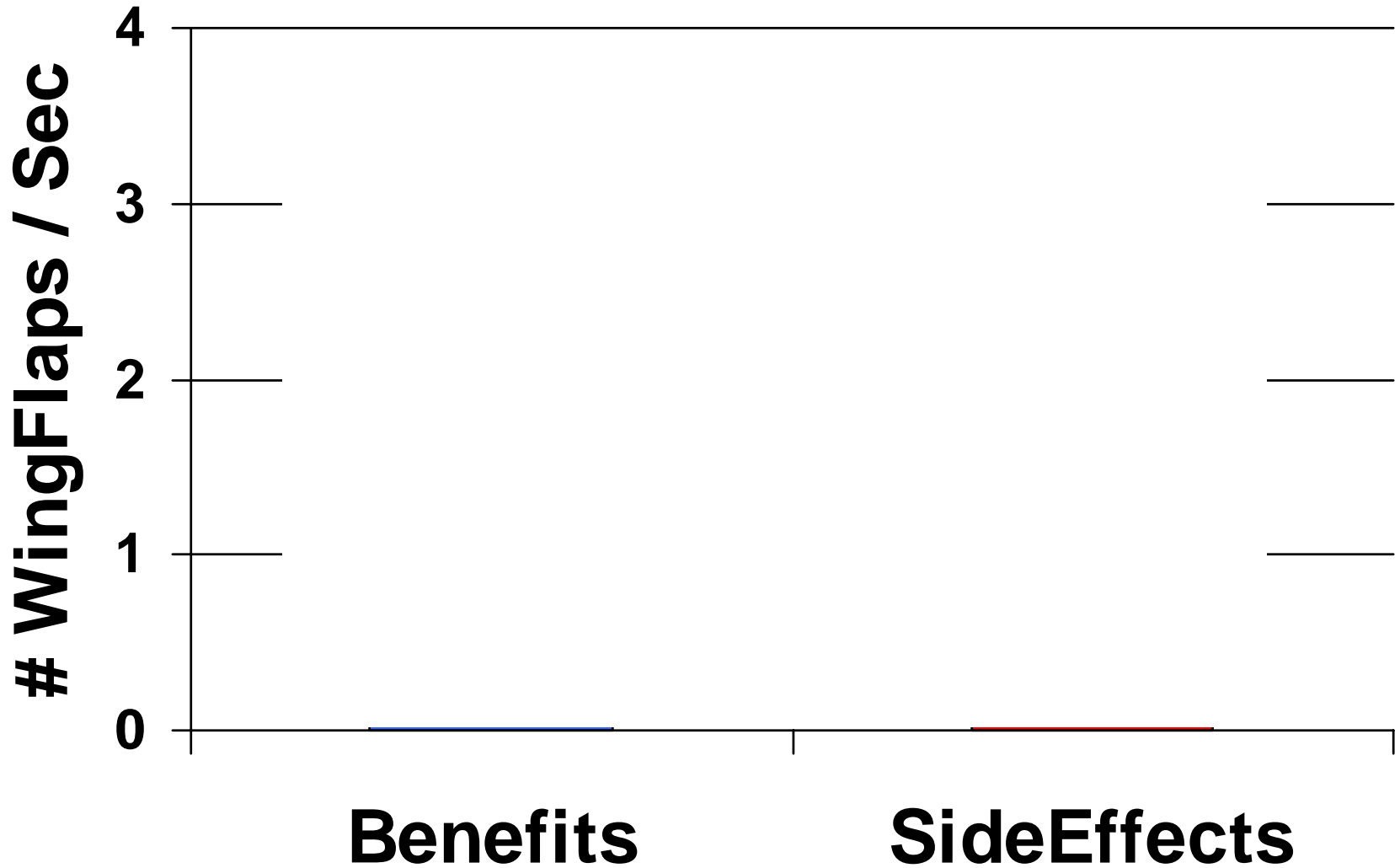
Nasonex: Benefits/End



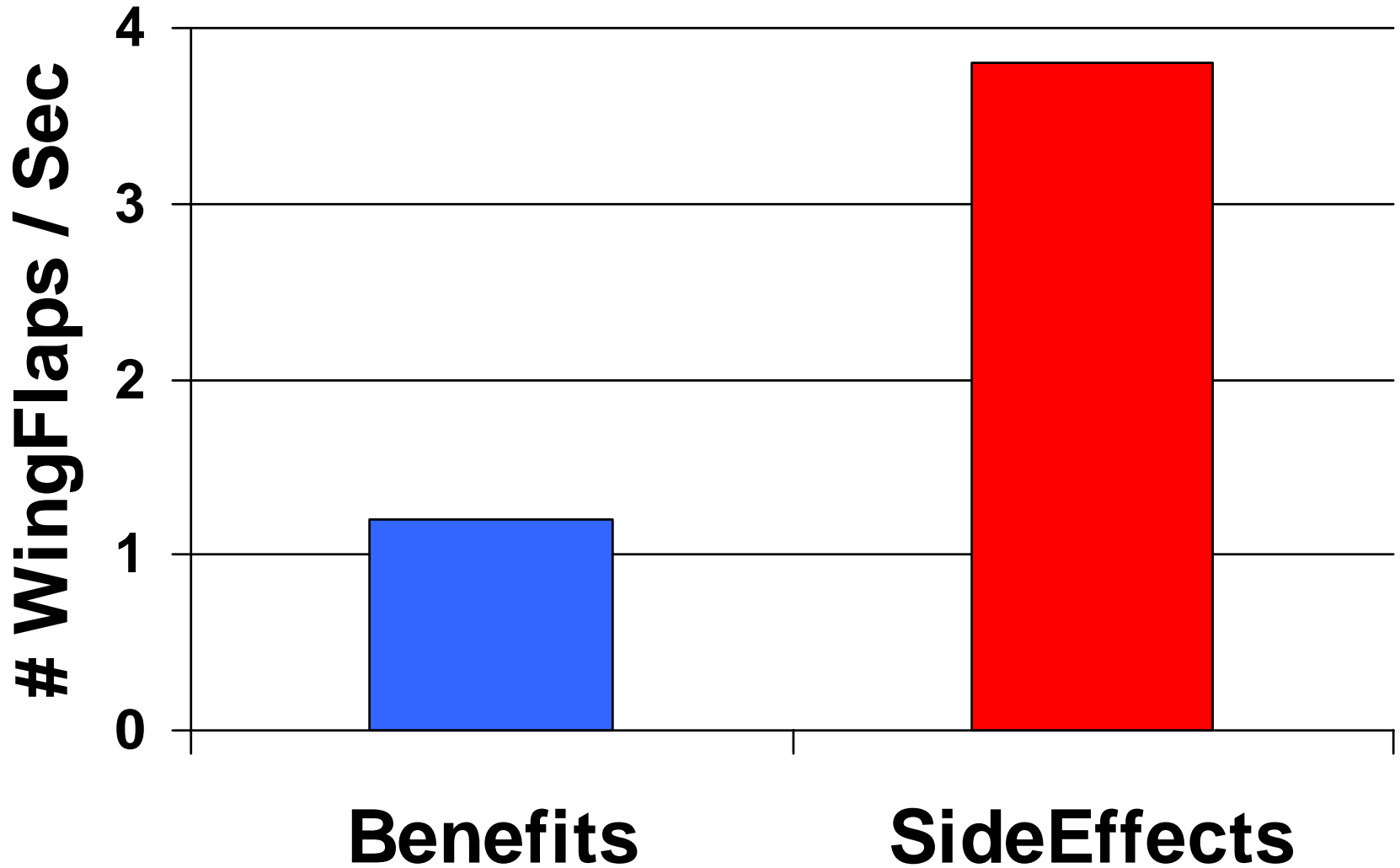
**TO TREAT AND HELP
PREVENT CONGESTION**

Talk to your doctor

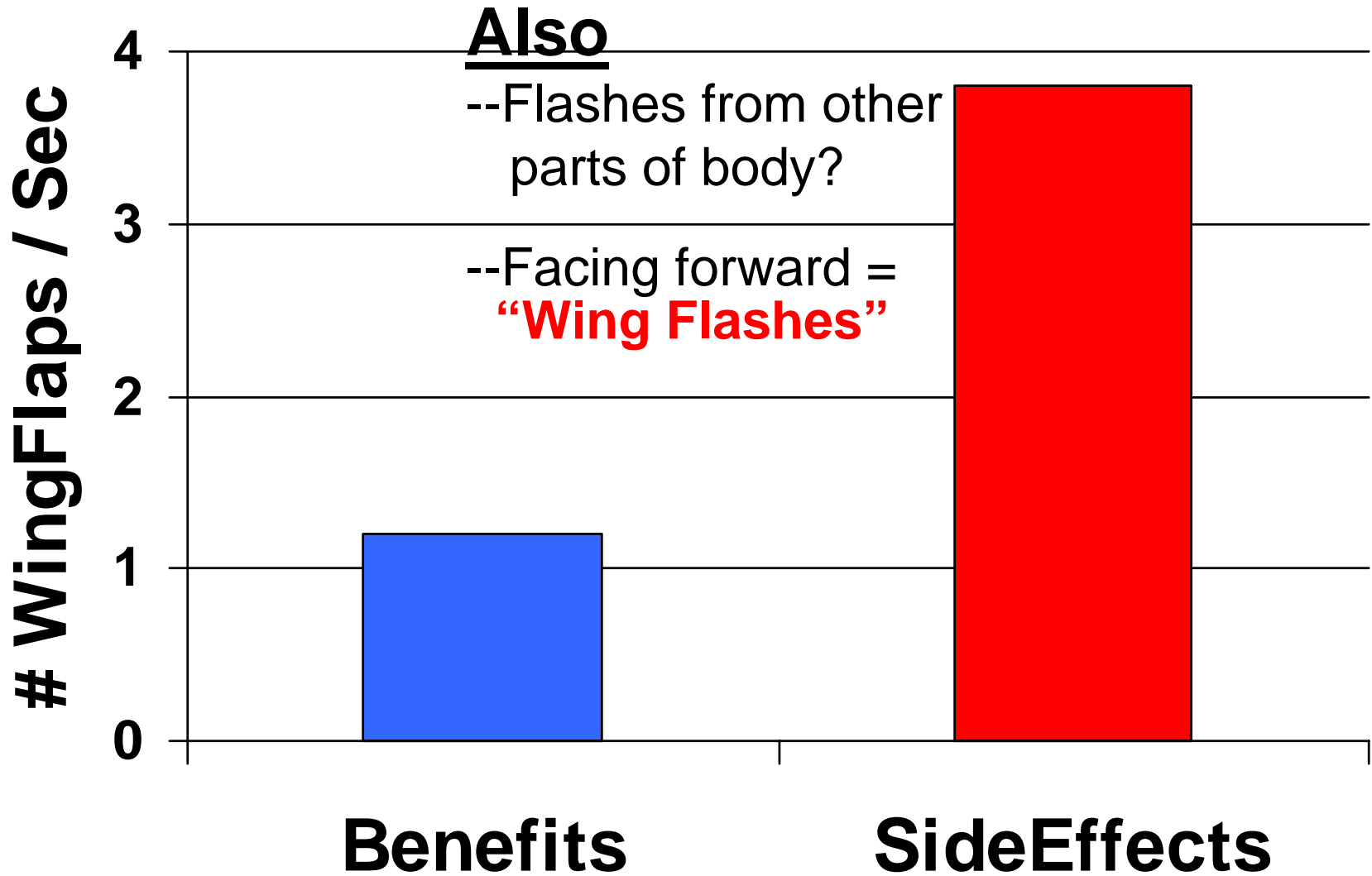
WingFlaps



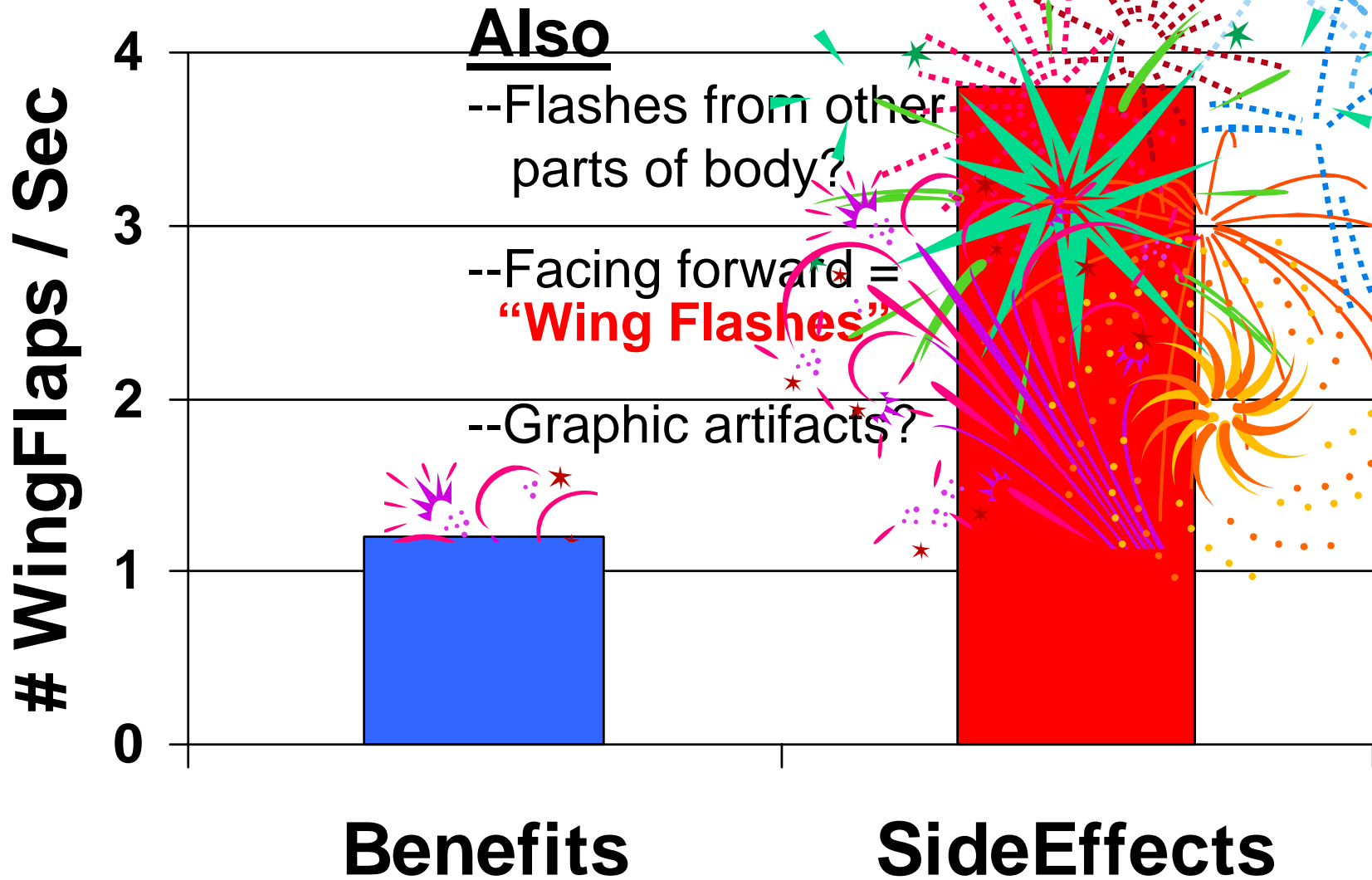
WingFlaps



WingFlaps + WingFlashes



WingFlaps + WingFlashes



Nasonex



- WingFlaps
- WingFlashes
- Sparkly

Nasonex



- WingFlaps
- WingFlashes
- Sparkly

- 
- 1) Divided attention
 - 2) Decreased knowledge

Nasonex



- WingFlaps
- WingFlashes
- Sparkly

- 
- 1) Divided attention
 - 2) Decreased knowledge
 - 3) Comments

“There weren’t any side effects.”

Speaker Effects

Speaker Effects

Typical Ad

Side effects

- Spoken by narrator
- Voice off-screen

New Approaches

Nexium

**My doctor said that
headaches, diarrhea ...**



Nexium

**My doctor said that
headaches, diarrhea ...**

and abdominal pain ...



Nexium

**My doctor said that
headaches, diarrhea ...**

and abdominal pain ...

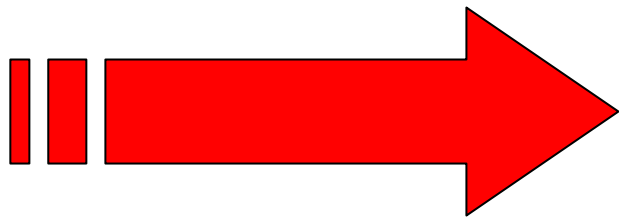
**could be side effects
of Nexium.**



Nexium



- Chunking
- Personalization
- Positive affect



- 1) Increased knowledge**
- 2) Acceptance**
- 3) Comments**

“They seem OK with the side effects.”

Ortho Evra

**... there are risks
especially for some
people**



Ortho Evra

**... there are risks
especially for some
people**

**...how do I know
I'm one of them?**



Ortho Evra

**... there are risks
especially for some
people**

**...how do I know
I'm one of them?**

**I ask you questions and you answer honestly
because serious risks include heart attack,
stroke, and blood clots.**

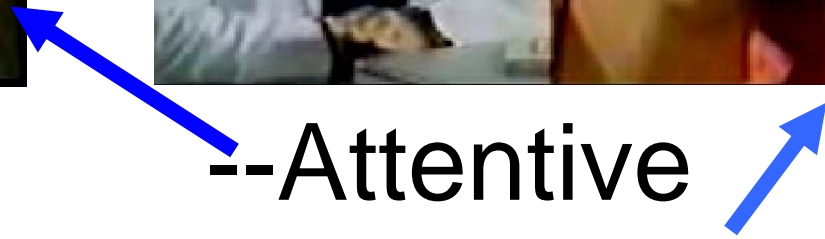


Ortho Evra



--Chunking
--Personalization

--Attentive
--Positive Affect



Ortho Evra

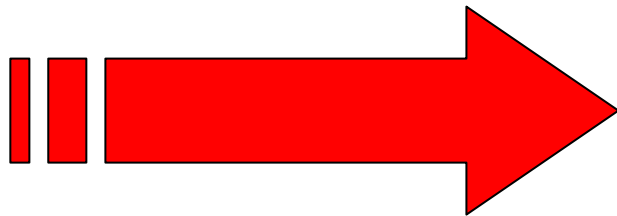


--Chunking

--Personalization

--Attentive

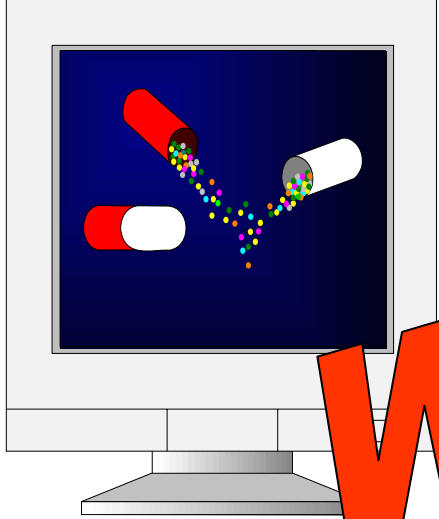
--Positive Affect



1) Increased knowledge

2) Attentiveness

3) Acceptance



Why hard?

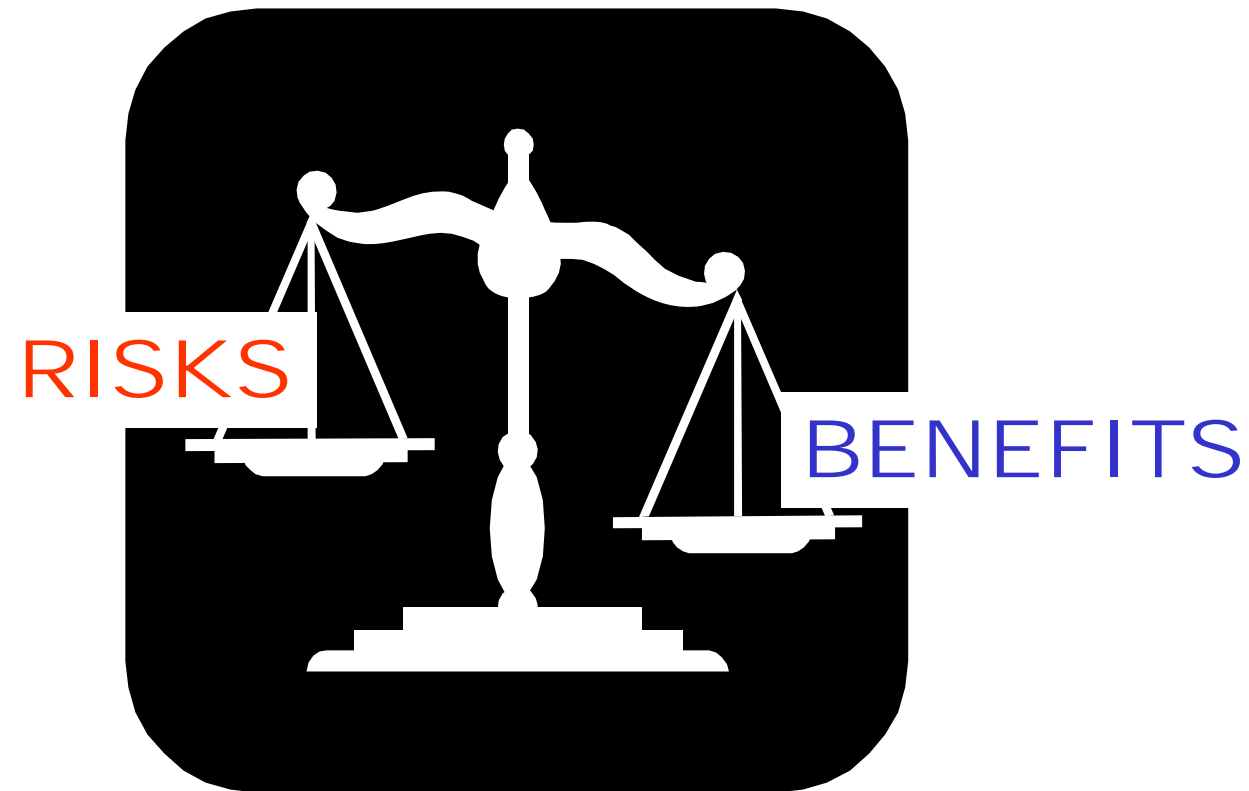
Factors

- Readability
- Location
- Speed
- Divided Attention
- Speaker Effects
- etc.

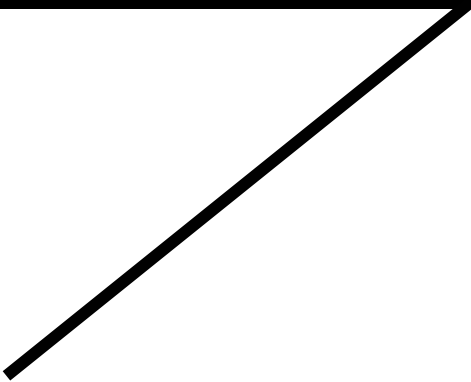
Conclusions

Current Practices

Unfair Balance

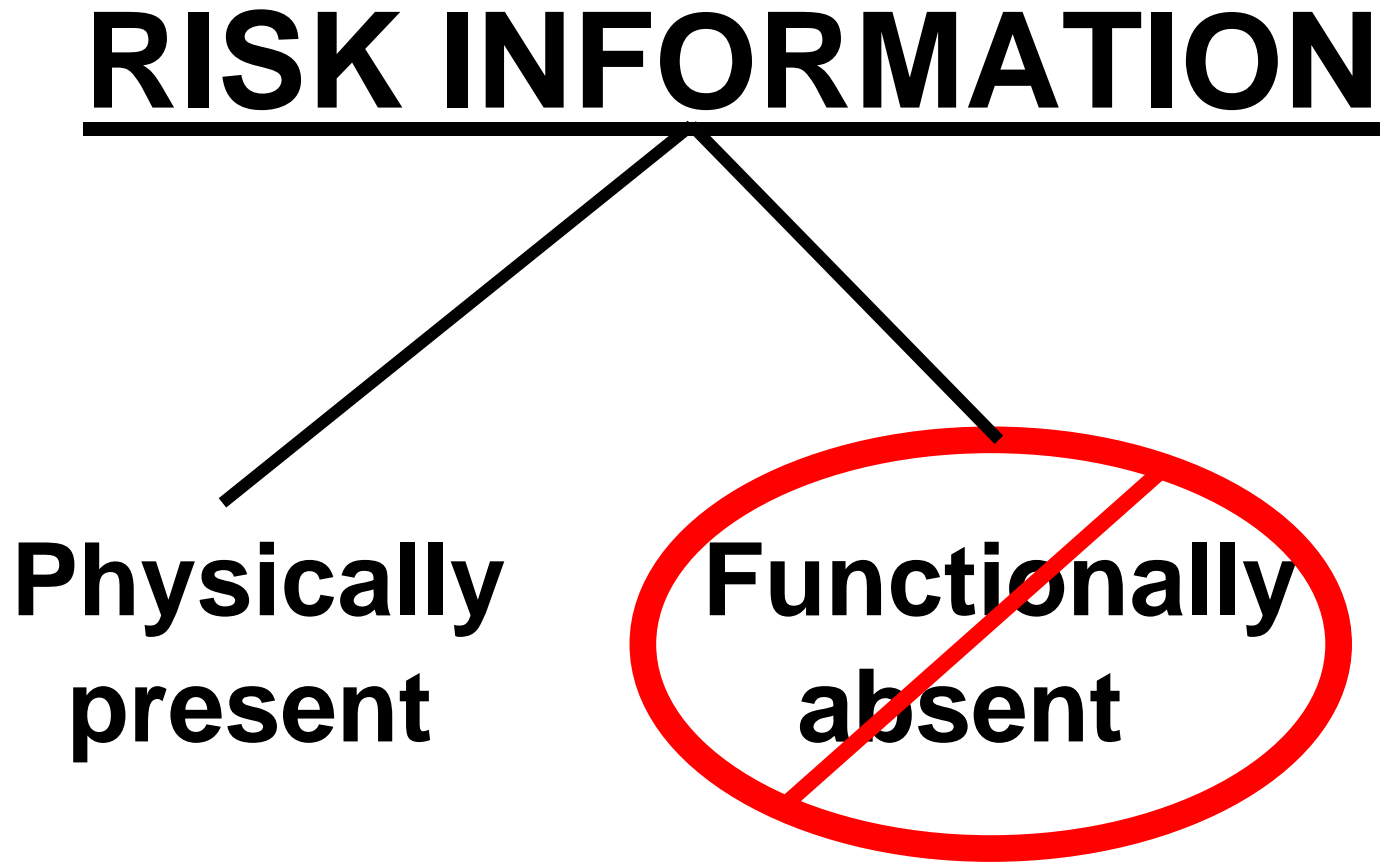


RISK INFORMATION



**Physically
present**

RISK INFORMATION



```
graph TD; A["RISK INFORMATION"] --> B["Physically present"]; A --> C["Functionally absent"]
```

Physically present

Functionally absent

Rush to judgment ?

Rush to judgment ?

Beware & Compare

Rush to judgment ?

Beware & Compare

Similar results

- pharmacy leaflets
- medication guides
- patient package inserts
- product websites
- professional label
- OTC packages

Not just DTC!

Rush to judgment ?

Beware & Compare

Similar results

- pharmacy leaflets
- medication guides
- patient package inserts
- product websites
- professional label
- OTC packages

1) Risk information

- less accessible than benefit info

Not just DTC!

Rush to judgment ?

Beware & Compare

Similar results

- pharmacy leaflets
- medication guides
- patient package inserts
- product websites
- professional label
- OTC packages

1) Risk information

- less accessible than benefit info

2) Risk performance

- worse

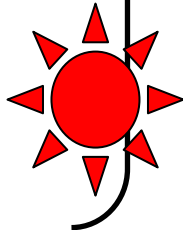
Not just DTC!

Rush to judgment ?

Beware & Compare

Similar results

- pharmacy leaflets
- medication guides
- patient package inserts
- product websites
- professional label
- OTC packages



Not just DTC!

1) Risk information

- less accessible than benefit info

2) Risk performance

- worse

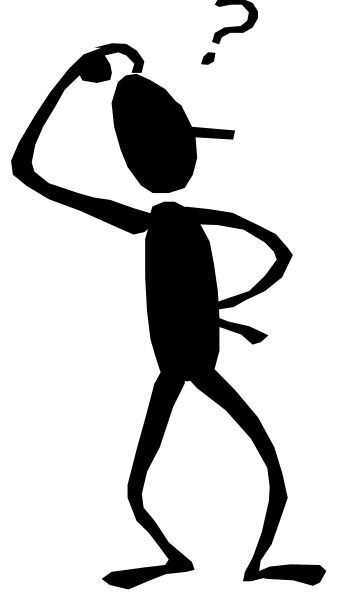
3) Risk performance

- increases with enhanced cognitive accessibility

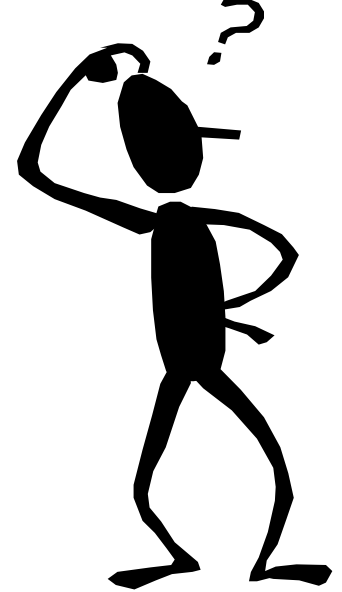
Recommendations

**To Regulate
or Not to Regulate** (*more*)

THAT IS THE QUESTION



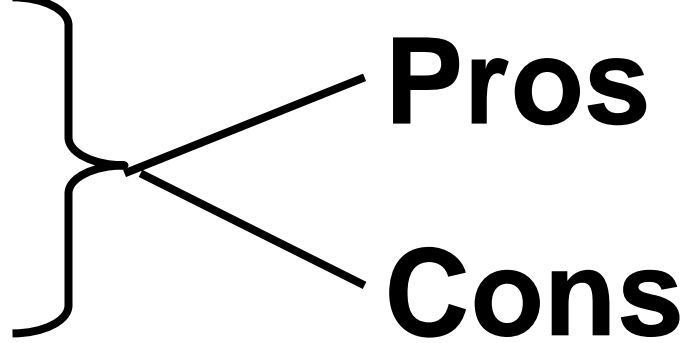
To Regulate or Not to Regulate *(more)* THAT IS THE QUESTION



“Whether 'tis nobler in the mind to suffer
The slings and arrows of **inaccessible risks**,
Or to take arms against a sea of troubles,
And by opposing end them?”

--with apologies to William Shakespeare....

**Should there be
an end to DTC?**





This research

- 1) **Unfair** balance of benefits vs. risks
 - 2) But it can be improved
 - 3) Better balance → improved performance
 - perception
 - comprehension
 - memory
- risks**

Evidence-based Approach



```
graph TD; A[Evidence-based Approach] --> B[Industry]; A --> C[Regulatory]
```

Industry

Regulatory

Evidence-based Approach

Positive Treatment

Benefits

Risks

Location



Speed



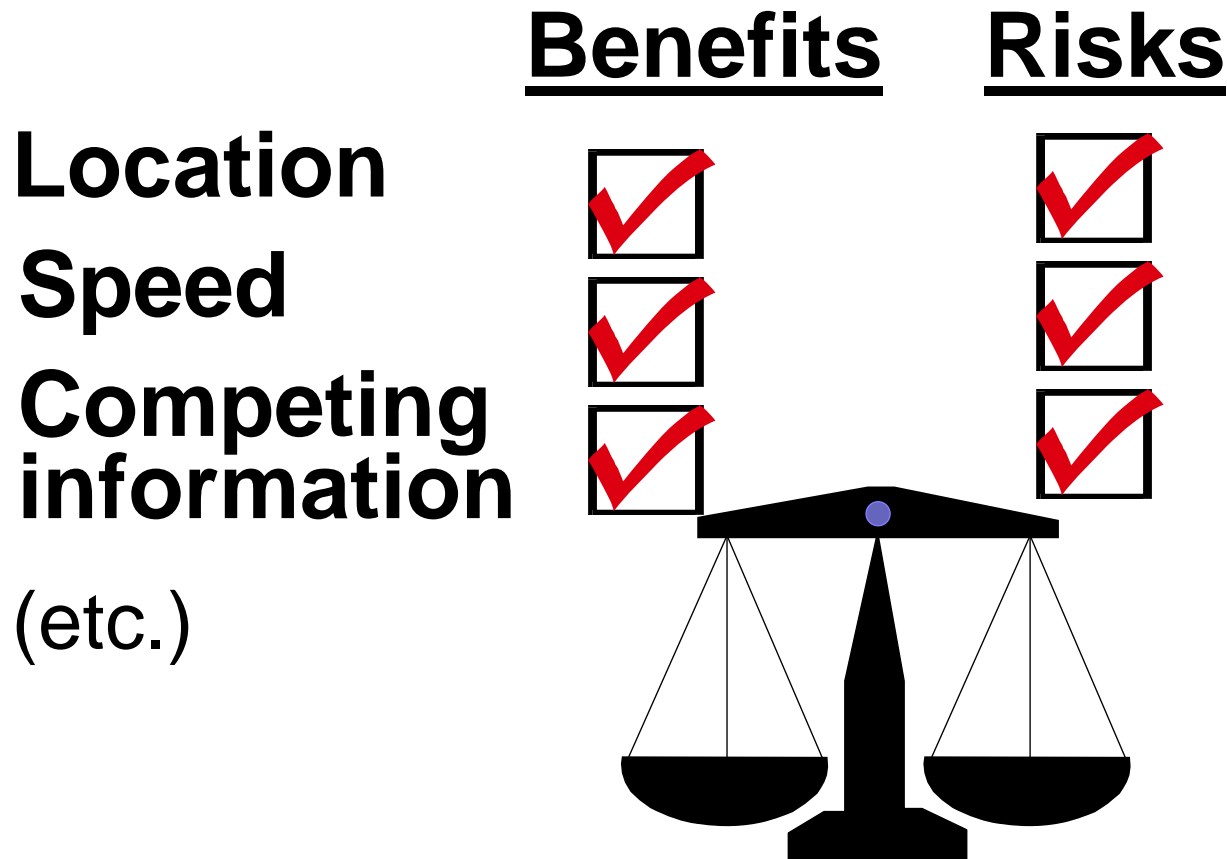
**Competing
information**



(etc.)

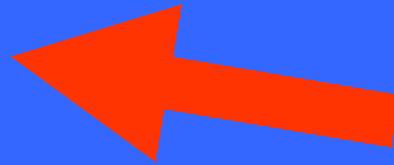
Evidence-based Approach

Positive Treatment

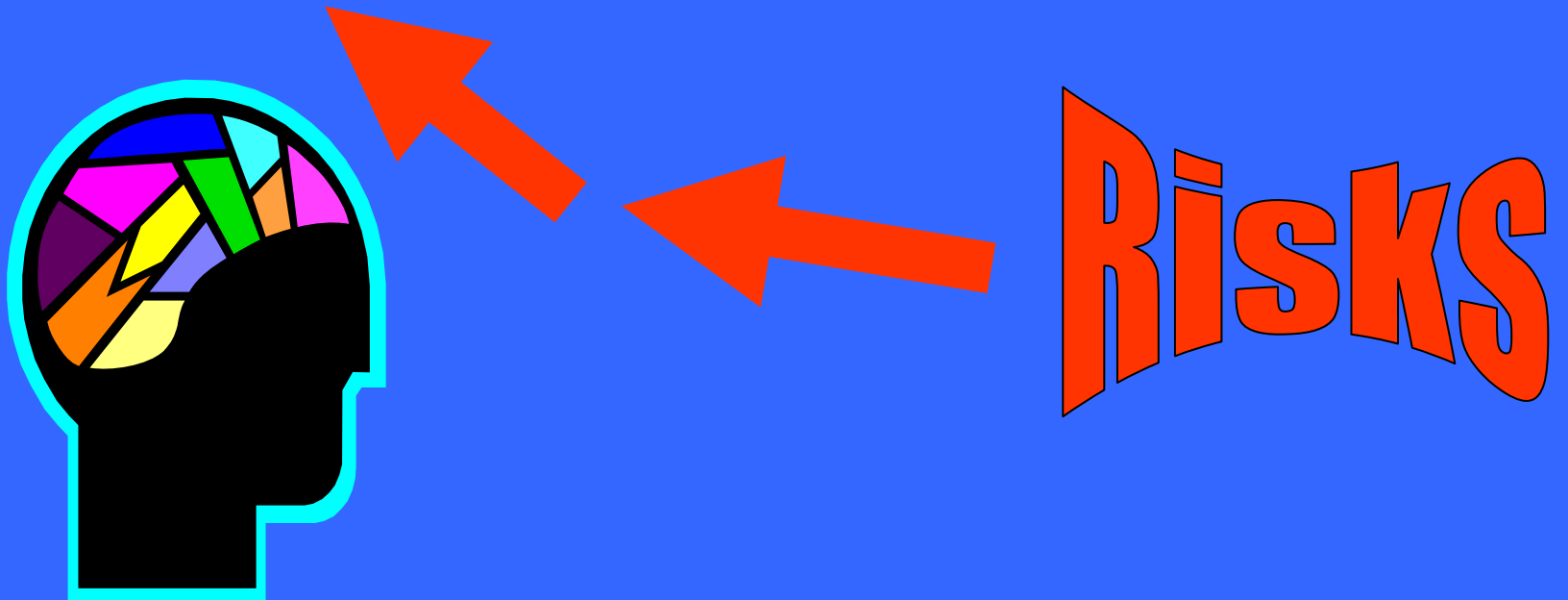


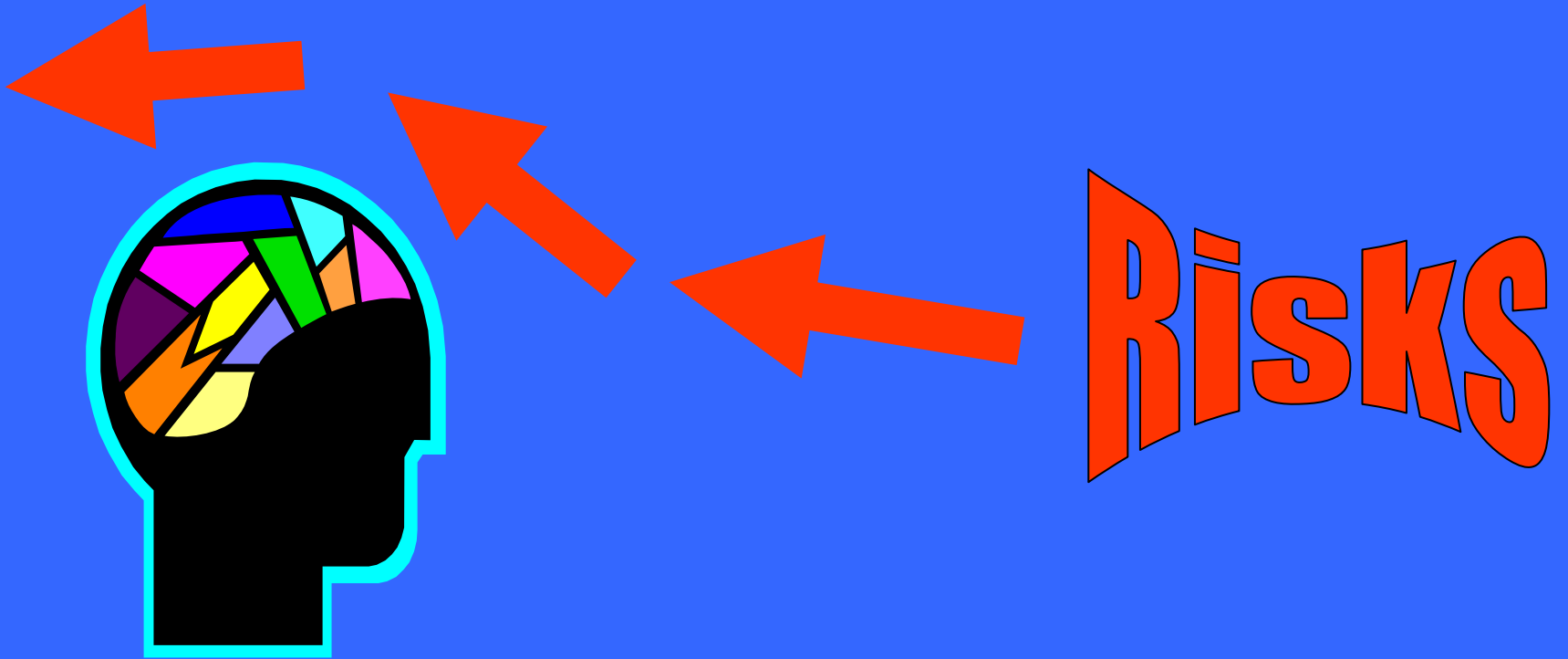


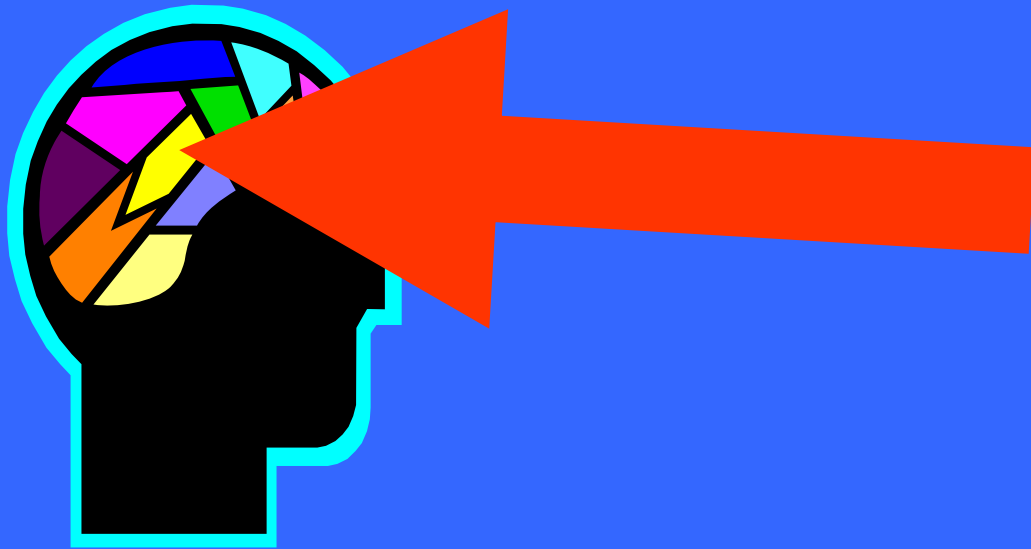
Risks



Risks







Risks



Comprehension of Benefits vs. Risks: Fair Balance in DTC?



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<http://www.duke.edu/~ruthday/medcog.html>